

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO, EASTERN DIVISION**

**DELANO HALE (# 490-551),
GERALD HAND (# 449-014),
JAMES HANNA (# 152-169),
JEROME HENDERSON (# 186-271),
WARREN K. HENNESS (# 287-375),
DANNY HILL (# 189-528),
GENESIS HILL (# 250-830),
TIMOTHY HOFFNER (# 315-988),
GARY HUGHBANKS (# 362-032),
LAMONT HUNTER (# 559-366),
PERCY HUTTON (# 195-620),
AHMAD ISSA (# 364-585),
ANDRE JACKSON (# 203-859),
CLEVELAND JACKSON (# 429-404),
KAREEM JACKSON (# 354-156),
NATHANIEL JACKSON (#440-891),
DONALD KETTERER (# 465-959),
JUAN KINLEY (# 239-789),
LAWRENCE LANDRUM (# 189-982),
CARL LINDSEY (# 350-106),
CHARLES LORRAINE (# 194-013),
GREGORY LOTT (# 198547),
JOSE TRINIDAD LOZA (# 250-059),
RALPH LYNCH (# 382-728),
JAMES MAMMONE (#581-111),
FREDDIE MCNEILL, JR. (# 309-673),
JONATHAN MONROE (# 383-816),
SAMUEL MORELAND (# 190-490),
TYRONE NOLING (# 222-599),
DENNY OBERMILLER (#600-936),
JAMES O'NEAL (# 325-132),
GREGORY OSIE (# 628-383),
KERRY PEREZ (# 509-017),
WAYNE POWELL (# 559-624),
WALTER RAGLIN (# 338-114),
WILLIAM SAPP (# 337-278),
MICHAEL DEAN SCOTT (# 387-350),
BOBBY T. SHEPPARD (# 315-284),
DUANE SHORT (# 525-858),
GEORGE SKATZES (# 173-501),
DAVID SNEED (# 192-040),**

**DAWUD SPAULDING (#634-998),
WARREN SPIVEY (# 216-212),
JOHN DAVID STUMPF (# 181-258),
JAMES TRIMBLE (# 494-014),
MICHAEL TURNER (# 438-811),
RAYMOND TWYFORD (# 275-069),
ROBERT VAN HOOK (# 186-347),
WARREN WADDY (# 199-737),
MICHAEL WEBB (# 246-589),
HERSIE WESSON (# 563-308),
ANDRE WILLIAMS (# 209-534),
CLIFFORD WILLIAMS (#237-994),
ROBERT WILLIAMS (# 381-764),
JEFFREY WOGENSTAHL (# 269-357),**
**Chillicothe Correctional
15802 State Route 104
Chillicothe, Ohio 44601,**

and

**SIDDIQUE ABDULLAH HASAN
(# 130-559),
KEITH LAMAR (# 317-117),
EDWARD LANG (# 532-018),
JASON ROBB (# 308-919),
JAMES WERE (# 173-245),**
**Ohio State Penitentiary
878 Coitsville-Hubbard Road
Youngstown, Ohio 44505,**

and

**ALVA CAMPBELL, JR. (# 354-963),
KEVIN SCUDDER (# 209-848),
KENNETH SMITH (# 326-630),**
**Franklin Medical Center
P.O. Box 23658
Columbus, Ohio 43223**

and

**TIMOTHY DUNLAP (Idaho DOC #35385),
Idaho Maximum Security
P.O. Box 51
Boise, ID 83634**

Plaintiffs,

v.

JOHN KASICH, Governor,

Defendant,

GARY C. MOHR, Director,

Defendant,

RONALD ERDOS, Warden,

Defendant,

DONALD MORGAN,

Defendant,

STEPHEN GRAY,

Defendant,

EDWIN VOORHIES,

Defendant,

RICHARD THEODORE,

Defendant,

CHARLOTTE JENKINS, Warden,

Defendant,

JOHN COLEMAN, Warden,

Defendant,

UNNAMED AND ANONYMOUS

EXECUTION TEAM MEMBERS,

Defendants,

UNKNOWN PHARMACIES #1-100,

Defendants,

UNKNOWN PHARMACISTS #1-100,

Defendants,

and

UNKNOWN DRUG SUPPLIERS #1-25

Defendants

and

JOHN DOES #1-25

Defendants.

**Fourth Amended Omnibus Complaint for Injunctive and Declaratory
Relief, Attorney Fees, and Costs of Suit Pursuant to 42 U.S.C. § 1983 and
Other Related Causes of Action**

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Plaintiff, by and through counsel, hereby files this Fourth Amended Omnibus Complaint for Injunctive and Declaratory Relief, Attorney Fees, and Costs of Suit Pursuant to 42 U.S.C. § 1983 and other related causes of action against Defendants John Kasich, et al., (hereinafter the “Fourth Amended Omnibus Complaint”).¹ Plaintiff alleges and avers as follows.²

NATURE OF THE ACTION

1. Plaintiff brings this action under 42 U.S.C. § 1983 for violations and threatened violations of his rights secured by the United States Constitution.
2. Plaintiff also asserts claims for violation of the federal Racketeer Influenced and Corrupt Organizations Act (RICO), § 18 U.S.C. § 1961 *et seq.*
3. Plaintiff also asserts claims under state law that form part of the same case or controversy as the federal claims.

¹ Citations or references to ECF docket numbers in this Fourth Amended Omnibus Complaint refer to the docket in *Cooey v. Kasich*, Case No. 2:04-1156, or the docket in *In re Ohio Execution Protocol Litigation*, Case No. 2:11-1016, and will be designated as such.

² The defined term “Plaintiff” shall be used in the singular to refer to each and all inmates listed in the caption of this Fourth Amended Omnibus Complaint, unless otherwise specified as necessary for an individual inmate. Notwithstanding the collective use of the term Plaintiff, each inmate individually raises the following allegations and claims.

Likewise, any particular individual Plaintiff’s “Plaintiff’s Complaint” includes the sum total of the Fourth Amended Omnibus Complaint as applicable to him and his Amended Individual Supplemental Complaint, if any.

4. As to his § 1983 claims, Plaintiff seeks equitable, injunctive, and declaratory relief, as well as attorney's fees and costs of suit.
5. As to his remaining federal or state law claims, Plaintiff seeks equitable, injunctive, and declaratory relief, as well as attorney's fees and costs of suit.
6. The federal constitutional claims in this Fourth Amended Omnibus Complaint, as raised against all Defendants including the new Defendants, are cognizable under 42 U.S.C. § 1983. *Baze v. Rees*, 553 U.S. 35 (2008); *Hill v. McDonough*, 547 U.S. 573 (2006); *Nelson v. Campbell*, 541 U.S. 637 (2004); *Adickes v. S. H. Kress & Co.*, 398 U.S. 144 (1970); *Lugar v. Edmondson Oil Co.*, 457 U.S. 922 (1982); *Dennis v. Sparks*, 449 U.S. 24 (1980).

JURISDICTION AND VENUE

7. This action arises under 42 U.S.C. § 1983 for violations of the First, Sixth, Eighth, Ninth, and Fourteenth Amendments of the United States Constitution, as well as provisions of federal statutory or common law. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 (federal question), 28 U.S.C. § 1343 (civil rights violations and equitable relief under an act of Congress), 18 U.S.C. § 1964(c) (jurisdiction over civil RICO actions), 28 U.S.C. § 2201 (declaratory relief), and 28 U.S.C. § 2202 (preliminary and permanent injunctive relief).

8. This Court also has supplemental jurisdiction over Plaintiff's state law claims under 28 U.S.C. § 1367 because they are so related to one or more claims in this action raised under 42 U.S.C. § 1983 for which this Court has original federal question jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.
9. This Court has personal jurisdiction over Defendants as they are residents of the State of Ohio, or are presently located in the State of Ohio, or are elected or appointed officials of the State of Ohio or otherwise acting on behalf of the State of Ohio, or have sought confidentiality and other protections under Ohio law concerning activities which are the subject of this action, or conduct business in the State of Ohio.
10. Venue is proper in this judicial district pursuant to 18 U.S.C. § 1965 (for RICO claims) and 28 U.S.C. § 1391(b) because this is where Defendants can be found and transact their affairs and because a substantial part of the events or omissions giving rise to the claims occurred in this District.

PARTIES

A. Plaintiffs

11. **Plaintiff Stanley Adams** is a United States citizen and a resident of the State of Ohio.

- a. Adams is currently a death-sentenced inmate in the custody of Defendants.
 - b. Adams is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #420-071.
 - c. **Plaintiff Adams has a scheduled execution date of February 16, 2022.**
12. **Plaintiff David Allen** is a United States citizen and a resident of the State of Ohio.
- a. Allen is currently a death-sentenced inmate in the custody of Defendants.
 - b. Allen is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #246-920.
 - c. Plaintiff Allen does not have a scheduled execution date.
13. **Plaintiff Abdul Awkal** is a United States citizen and a resident of the State of Ohio.
- a. Awkal is currently a death-sentenced inmate in the custody of Defendants.
 - b. Awkal is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him

incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #267-328.

- a. Plaintiff Awkal's execution is stayed and preliminarily enjoined by order of this Court.

14. **Plaintiff Tyrone Ballew** is a United States citizen and a resident of the State of Ohio.

- a. Ballew is currently a death-sentenced inmate in the custody of Defendants.
- b. Ballew is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #261-875.

- c. Plaintiff Ballew does not have a scheduled execution date.

15. **Plaintiff Richard Bays** is a United States citizen and a resident of the State of Ohio.

- a. Bays is currently a death-sentenced inmate in the custody of Defendants.
- b. Bays is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction ("DRC"), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #325-266.

- c. Plaintiff Bays does not have a scheduled execution date.

16. **Plaintiff Anthony Belton** is a United States citizen and a resident of the State of Ohio.

- a. Bays is currently a death-sentenced inmate in the custody of Defendants.
- b. Bays is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #659-445.
- c. Plaintiff Belton does not have a scheduled execution date.

17. **Plaintiff Robert Bethel** is a United States citizen and a resident of the State of Ohio.

- a. Bethel is currently a death-sentenced inmate in the custody of Defendants.
- b. Bethel is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #455-970.
- c. Plaintiff Bethel does not have a scheduled execution date.

18. **Plaintiff Melvin Bonnell** is a United States citizen and a resident of the State of Ohio.

- a. Bonnell is currently a death-sentenced inmate in the custody of Defendants.

b. Bonnell is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #204-019.

c. Plaintiff Bonnell has a scheduled execution date of February 12, 2020.

19. **Plaintiff David Braden** is a United States citizen and a resident of the State of Ohio.

a. Braden is currently a death-sentenced inmate in the custody of Defendants.
b. Braden is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #380-366.

c. Plaintiff Braden does not have a scheduled execution date.

20. **Plaintiff Romell Broom** is a United States citizen and a resident of the State of Ohio.

a. Broom is currently a death-sentenced inmate in the custody of Defendants.
b. Broom is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #187-343.

c. Plaintiff Broom has a scheduled execution date of June 17, 2020.

21. **Plaintiff Quisi Bryan** is a United States citizen and a resident of the State of Ohio.

- a. Bryan is currently a death-sentenced inmate in the custody of Defendants.
- b. Bryan is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #399-595.
- c. Plaintiff Bryan does not have a scheduled execution date.

22. **Plaintiff Cedric Carter** is a United States citizen and a resident of the State of Ohio.

- a. Carter is currently a death-sentenced inmate in the custody of Defendants.
- b. Carter is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #262-433.
- c. Plaintiff Carter does not have a scheduled execution date.

23. **Plaintiff Sean Carter** is a United States citizen and a resident of the State of Ohio.

- a. Carter is currently a death-sentenced inmate in the custody of Defendants.

b. Carter is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #356-659.

c. Plaintiff Carter does not have a scheduled execution date.

24. **Plaintiff August Cassano** is a United States citizen and a resident of the State of Ohio.

a. Cassano is currently a death-sentenced inmate in the custody of Defendants.

b. Cassano is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #145-242.

c. Plaintiff Cassano does not have a scheduled execution date.

25. **Plaintiff Steven Cepec** is a United States citizen and a resident of the State of Ohio.

a. Cepec is currently a death-sentenced inmate in the custody of Defendants.

b. Cepec is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #679-701.

c. Plaintiff Cepec does not have a scheduled execution date.

26. **Plaintiff Davel Chinn** is a United States citizen and a resident of the State of Ohio.

- a. Chinn is currently a death-sentenced inmate in the custody of Defendants.
- b. Chinn is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #214-241.
- c. Plaintiff Chinn does not have a scheduled execution date.

27. **Plaintiff Douglas Coley** is a United States citizen and a resident of the State of Ohio.

- a. Coley is currently a death-sentenced inmate in the custody of Defendants.
- b. Coley is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #361-444.

c. Plaintiff Coley has a scheduled execution date of August 12, 2020.

28. **Plaintiff James T. Conway** is a United States citizen and a resident of the State of Ohio.

- a. Conway is currently a death-sentenced inmate in the custody of Defendants.

- b. Conway is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #457-203.
 - c. Plaintiff Conway does not have a scheduled execution date.
29. **Plaintiff Jeronique Cunningham** is a United States citizen and a resident of the State of Ohio.
- a. Cunningham is currently a death-sentenced inmate in the custody of Defendants.
 - b. Cunningham is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #428-323.
 - c. Plaintiff Cunningham does not have a scheduled execution date.
30. **Plaintiff Roland Davis** is a United States citizen and a resident of the State of Ohio.
- a. Davis is currently a death-sentenced inmate in the custody of Defendants.
 - b. Davis is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #499-211.
 - c. Plaintiff Davis does not have a scheduled execution date.

31. **Plaintiff Archie Dixon** is a United States citizen and a resident of the State of Ohio.

- a. Dixon is currently a death-sentenced inmate in the custody of Defendants.
- b. Dixon is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #325-702.

c. Plaintiff Dixon has a scheduled execution date of June 23, 2021.

32. **Plaintiff John Drummond** is a United States citizen and a resident of the State of Ohio.

- a. Drummond is currently a death-sentenced inmate in the custody of Defendants.
- b. Drummond is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #462-868.

c. Plaintiff Drummond has a scheduled execution date of April 21, 2022.

33. **Plaintiff Timothy Dunlap** is a United States citizen and a resident of the State of Idaho.

- a. Dunlap is currently under a death sentence ordered by an Ohio court following conviction and sentencing under Ohio law.

- b. Dunlap is also under a death sentence ordered by an Idaho court following conviction and sentencing under Idaho law, which death sentence preceded his Ohio death sentence, and thus he is in the custody of the State of Idaho Department of Correction (“IDRC”).
- c. Dunlap is under the control and supervision of the Idaho Department of Rehabilitation and Correction (“IDRC”), who have him incarcerated at the Idaho Maximum Security Institution, 13400 South Pleasant Valley Road, Kuna, Idaho 83634 under IDRC Inmate #35385.
- d. Plaintiff Dunlap does not have a scheduled execution date in Ohio.

34. **Plaintiff Phillip Elmore** is a United States citizen and a resident of the State of Ohio.

- a. Elmore is currently a death-sentenced inmate in the custody of Defendants.
- b. Elmore is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #458-539.
- c. Plaintiff Elmore does not have a scheduled execution date in Ohio.

35. **Plaintiff Gregory Esparza** is a United States citizen and a resident of the State of Ohio.

- a. Esparza is currently a death-sentenced inmate in the custody of Defendants.

- b. Esparza is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #179-450.
- c. Plaintiff Esparza does not have a scheduled execution date in Ohio.

36. **Plaintiff Angelo Fears** is a United States citizen and a resident of the State of Ohio.

- a. Fears is currently a death-sentenced inmate in the custody of Defendants.
- b. Fears is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #352-193.

c. Plaintiff Fears has a scheduled execution date of October 17, 2019.

37. **Plaintiff Stanley Fitzpatrick** is a United States citizen and a resident of the State of Ohio.

- a. Fitzpatrick is currently a death-sentenced inmate in the custody of Defendants.
- b. Fitzpatrick is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #419-722.

c. Plaintiff Fitzpatrick has a scheduled execution date of October 14, 2020.

38. **Plaintiff Antonio Sanchez Franklin** is a United States citizen and a resident of the State of Ohio.

- a. Franklin is currently a death-sentenced inmate in the custody of Defendants.
- b. Franklin is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #363-374.
- c. Plaintiff Franklin does not have a scheduled execution date.

39. **Plaintiff James Frazier** is a United States citizen and a resident of the State of Ohio.

- a. Frazier is currently a death-sentenced inmate in the custody of Defendants.
- b. Frazier is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #497-904.

c. Plaintiff Frazier has a scheduled execution date of October 20, 2021.

40. **Plaintiff Clarence Fry** is a United States citizen and a resident of the State of Ohio.

- a. Fry is currently a death-sentenced inmate in the custody of Defendants.
- b. Fry is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #510-923.
- c. Plaintiff Fry does not have a scheduled execution date.

41. **Plaintiff Larry Gapen** is a United States citizen and a resident of the State of Ohio.

- a. Gapen is currently a death-sentenced inmate in the custody of Defendants.
- b. Gapen is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #413-724.
- c. Plaintiff Gapen does not have a scheduled execution date.

42. **Plaintiff Delano Hale** is a United States citizen and a resident of the State of Ohio.

- a. Hale is currently a death-sentenced inmate in the custody of Defendants.
- b. Hale is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him

incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #490-551.

c. Plaintiff Hale does not have a scheduled execution date.

43. **Plaintiff Gerald Hand** is a United States citizen and a resident of the State of Ohio.

a. Hand is currently under a death sentence ordered by an Ohio court following conviction and sentencing under Ohio law.

b. Hand is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #449-014.

c. Plaintiff Hand does not have a scheduled execution date in Ohio.

44. **Plaintiff James Hanna** is a United States citizen and a resident of the State of Ohio.

a. Hanna is currently a death-sentenced inmate in the custody of Defendants.

b. Hanna is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #152-169.

c. **Plaintiff Hanna has a scheduled execution date of December 11, 2019.**

45. **Plaintiff Siddique Abdullah Hasan** is a United States citizen and a resident of the State of Ohio.

- a. Hasan is currently a death-sentenced inmate in the custody of Defendants.
- b. Hasan is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at Ohio State Penitentiary, 878 Coitsville-Hubbard Road, Youngstown, Ohio, under Inmate #130-559.

c. Plaintiff Hasan does not have a scheduled execution date.

46. **Plaintiff Jerome Henderson** is a United States citizen and a resident of the State of Ohio.

- a. Henderson is currently a death-sentenced inmate in the custody of Defendants.
- b. Henderson is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #186-271.

c. Plaintiff Henderson does not have a scheduled execution date.

47. **Plaintiff Warren K. Henness** is a United States citizen and a resident of the State of Ohio.

- a. Henness is currently a death-sentenced inmate in the custody of Defendants.

b. Henness is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #287-375.

c. Plaintiff Henness has a scheduled execution date of February 13, 2019.

48. **Plaintiff Danny Hill** is a United States citizen and a resident of the State of Ohio.

a. Hill is currently a death-sentenced inmate in the custody of Defendants.

b. Hill is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #189-528.

c. Plaintiff Hill does not have a scheduled execution date.

49. **Plaintiff Genesis Hill** is a United States citizen and a resident of the State of Ohio.

a. Hill is currently a death-sentenced inmate in the custody of Defendants.

b. Hill is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #250-830.

- c. Plaintiff Hill does not have a scheduled execution date.
50. **Plaintiff Timothy Hoffner** is a United States citizen and a resident of the State of Ohio.
- a. Hoffner is currently a death-sentenced inmate in the custody of Defendants.
 - b. Hoffner is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #315-988.
 - c. **Plaintiff Hoffner has a scheduled execution date of August 11, 2021.**
51. **Plaintiff Gary Hughbanks** is a United States citizen and a resident of the State of Ohio.
- a. Hughbanks is currently a death-sentenced inmate in the custody of Defendants.
 - b. Hughbanks is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #362-032.
 - c. Plaintiff Hughbanks does not have a scheduled execution date.
52. **Plaintiff Lamont Hunter** is a United States citizen and a resident of the State of Ohio.

- a. Hunter is currently a death-sentenced inmate in the custody of Defendants.
 - b. Hunter is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #559-366.
 - c. Plaintiff Hunter does not have a scheduled execution date.
53. **Plaintiff Percy Hutton** is a United States citizen and a resident of the State of Ohio.
- a. Hutton is currently a death-sentenced inmate in the custody of Defendants.
 - b. Hutton is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #195-620.
 - c. Plaintiff Hutton does not have a scheduled execution date.
54. **Plaintiff Ahmad Issa** is a United States citizen and a resident of the State of Ohio.
- a. Issa is currently a death-sentenced inmate in the custody of Defendants.
 - b. Issa is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him

incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #364-585.

c. Plaintiff Issa does not have a scheduled execution date.

55. **Plaintiff Andre Jackson** is a United States citizen and a resident of the State of Ohio.

a. Jackson is currently a death-sentenced inmate in the custody of Defendants.

b. Jackson is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #203-859.

c. Plaintiff Jackson does not have a scheduled execution date.

56. **Plaintiff Cleveland Jackson** is a United States citizen and a resident of the State of Ohio.

a. Jackson is currently a death-sentenced inmate in the custody of Defendants.

b. Jackson is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #429-404.

c. Plaintiff Jackson has a scheduled execution date of September 13, 2018.

57. **Plaintiff Kareem Jackson** is a United States citizen and a resident of the State of Ohio.

- a. Jackson is currently a death-sentenced inmate in the custody of Defendants.
- b. Jackson is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #354-156.
- c. **Plaintiff Jackson has a scheduled execution date of July 10, 2019.**

58. **Plaintiff Nathaniel Jackson** is a United States citizen and a resident of the State of Ohio.

- a. Jackson is currently a death-sentenced inmate in the custody of Defendants.
- b. Jackson is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #440-891.
- c. Plaintiff Jackson does not have a scheduled execution date.

59. **Plaintiff Donald Ketterer** is a United States citizen and a resident of the State of Ohio.

- a. Ketterer is currently a death-sentenced inmate in the custody of Defendants.

- b. Ketterer is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #465-959.
 - c. Plaintiff Ketterer does not have a scheduled execution date.
60. **Plaintiff Juan Kinley** is a United States citizen and a resident of the State of Ohio.
- a. Kinley is currently a death-sentenced inmate in the custody of Defendants.
 - b. Kinley is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #239-789.
 - c. Plaintiff Kinley does not have a scheduled execution date.
61. **Plaintiff Keith LaMar** is a United States citizen and a resident of the State of Ohio.
- a. LaMar is currently a death-sentenced inmate in the custody of Defendants.
 - b. LaMar is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at Ohio State Penitentiary, 878 Coitsville-Hubbard Road, Youngstown, Ohio, under Inmate #317-117.
 - c. Plaintiff LaMar does not have a scheduled execution date.

62. **Plaintiff Lawrence Landrum** is a United States citizen and a resident of the State of Ohio.
- a. Landrum is currently a death-sentenced inmate in the custody of Defendants.
 - b. Landrum is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #189-982.
 - c. **Plaintiff Landrum has a scheduled execution date of December 9, 2021.**
63. **Plaintiff Edward Lang** is a United States citizen and a resident of the State of Ohio.
- a. Lang is currently a death-sentenced inmate in the custody of Defendants.
 - b. Lang is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at Ohio State Penitentiary, 878 Coitsville-Hubbard Road, Youngstown, Ohio, under Inmate #532-018.
 - c. Plaintiff Lang does not have a scheduled execution date.
64. **Plaintiff Carl Lindsey** is a United States citizen and a resident of the State of Ohio.
- a. Lindsey is currently a death-sentenced inmate in the custody of Defendants.

- b. Lindsey is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #350-106.
- c. Plaintiff Lindsey does not have a scheduled execution date.

65. **Plaintiff Charles Lorraine** is a United States citizen and a resident of the State of Ohio.

- a. Lorraine is currently a death-sentenced inmate in the custody of Defendants.
- b. Lorraine is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #194-013.
- c. Plaintiff Lorraine’s execution is stayed and preliminarily enjoined by order of this Court.

66. **Plaintiff Gregory Lott** is a United States citizen and a resident of the State of Ohio.

- a. Lott is currently a death-sentenced inmate in the custody of Defendants.
- b. Lott is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #198-547.

c. Plaintiff Lott has a scheduled execution date of August 14, 2019.

67. **Plaintiff Jose Trinidad Loza** is a United States citizen and a resident of the State of Ohio.
- a. Loza is currently a death-sentenced inmate in the custody of Defendants.
- b. Loza is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #250-059.
- c. Plaintiff Loza does not have a scheduled execution date.
68. **Plaintiff Ralph Lynch** is a United States citizen and a resident of the State of Ohio.
- a. Lynch is currently a death-sentenced inmate in the custody of Defendants.
- b. Lynch is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #382-728.
- c. Plaintiff Lynch does not have a scheduled execution date.
69. **Plaintiff James Mammone** is a United States citizen and a resident of the State of Ohio.
- a. Mammone is currently a death-sentenced inmate in the custody of Defendants.

- b. Mammone is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #581-111.
 - c. Plaintiff Mammone does not have a scheduled execution date.
70. **Plaintiff Freddie McNeill, Jr.** is a United States citizen and a resident of the State of Ohio.
- a. McNeill is currently a death-sentenced inmate in the custody of Defendants.
 - b. McNeill is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #309-673.
 - c. Plaintiff McNeill does not have a scheduled execution date.
71. **Plaintiff Jonathan Monroe** is a United States citizen and a resident of the State of Ohio.
- a. Monroe is currently a death-sentenced inmate in the custody of Defendants.
 - b. Monroe is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #383-816.
 - c. Plaintiff Monroe does not have a scheduled execution date.

72. **Plaintiff Samuel Moreland** is a United States citizen and a resident of the State of Ohio.

- a. Moreland is currently a death-sentenced inmate in the custody of Defendants.
- b. Moreland is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #190-490.
- c. Plaintiff Moreland does not have a scheduled execution date.

73. **Plaintiff Tyrone Noling** is a United States citizen and a resident of the State of Ohio.

- a. Noling is currently a death-sentenced inmate in the custody of Defendants.
- b. Noling is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #222-599.
- c. Plaintiff Noling does not have a scheduled execution date.

74. **Plaintiff Denny Obermiller** is a United States citizen and a resident of the State of Ohio.

- a. Obermiller is currently a death-sentenced inmate in the custody of Defendants.

- b. Obermiller is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #600-936.
- c. Plaintiff Obermiller does not have a scheduled execution date.

75. **Plaintiff James O’Neal** is a United States citizen and a resident of the State of Ohio.

- a. O’Neal is currently a death-sentenced inmate in the custody of Defendants.
- b. O’Neal is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #325-132.

c. Plaintiff O’Neal has a scheduled execution date of February 18, 2021.

76. **Plaintiff Gregory Osie** is a United States citizen and a resident of the State of Ohio.

- a. Osie is currently a death-sentenced inmate in the custody of DRC Defendants.
- b. Osie is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #628-383.

- c. Plaintiff Osie does not have a scheduled execution date.
77. **Plaintiff Kerry Perez** is a United States citizen and a resident of the State of Ohio.
- a. Perez is currently a death-sentenced inmate in the custody of Defendants.
 - b. Perez is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #509-017.
 - c. Plaintiff Perez does not have a scheduled execution date.
78. **Plaintiff Wayne Powell** is a United States citizen and a resident of the State of Ohio.
- a. Powell is currently a death-sentenced inmate in the custody of DRC Defendants.
 - b. Powell is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate # 559-624.
 - c. Plaintiff Powell does not have a scheduled execution date.
79. **Plaintiff Walter Raglin** is a United States citizen and a resident of the State of Ohio.
- a. Raglin is currently a death-sentenced inmate in the custody of Defendants.

- b. Raglin is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #338-114.
- c. Plaintiff Raglin does not have a scheduled execution date.

80. **Plaintiff Jason Robb** is a United States citizen and a resident of the State of Ohio.

- a. Robb is currently a death-sentenced inmate in the custody of Defendants.
- b. Robb is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at Ohio State Penitentiary, 878 Coitsville-Hubbard Road, Youngstown, Ohio, under Inmate #308-919.
- c. Plaintiff Robb does not have a scheduled execution date.

81. **Plaintiff William Sapp** is a United States citizen and a resident of the State of Ohio.

- a. Sapp is currently a death-sentenced inmate in the custody of Defendants.
- b. Sapp is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #337-278.
- c. Plaintiff Sapp does not have a scheduled execution date.

82. **Plaintiff Michael Dean Scott** is a United States citizen and a resident of the State of Ohio.

- a. Scott is currently a death-sentenced inmate in the custody of Defendants.
- b. Scott is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #387-350.
- c. Plaintiff Scott does not have a scheduled execution date.

83. **Plaintiff Kevin Scudder** is a United States citizen and a resident of the State of Ohio.

- a. Scudder is currently a death-sentenced inmate in the custody of Defendants.
- b. Scudder is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Franklin Medical Center, 1990 Harmon Ave, Columbus, Ohio under Inmate #209-848.
- c. Plaintiff Scudder does not have a scheduled execution date.

84. **Plaintiff Bobby T. Sheppard** is a United States citizen and a resident of the State of Ohio.

- a. Sheppard is currently a death-sentenced inmate in the custody of Defendants.

- b. Sheppard is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #315-284.
- c. Plaintiff Sheppard does not have a scheduled execution date.

85. **Plaintiff Duane Short** is a United States citizen and a resident of the State of Ohio.

- a. Short is currently a death-sentenced inmate in the custody of Defendants.
- b. Short is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #525-858.
- c. Plaintiff Short does not have a scheduled execution date.

86. **Plaintiff George Skatzes** is a United States citizen and a resident of the State of Ohio.

- a. Skatzes is currently a death-sentenced inmate in the custody of Defendants.
- b. Skatzes is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #173-501.
- c. Plaintiff Skatzes does not have a scheduled execution date.

87. **Plaintiff Kenneth Smith** is a United States citizen and a resident of the State of Ohio.
- a. Smith is currently a death-sentenced inmate in the custody of Defendants.
 - b. Smith is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Franklin Medical Center, 1990 Harmon Ave, Columbus, Ohio under Inmate #326-630.
 - c. Plaintiff Smith’s execution is stayed and preliminarily enjoined by order of this Court.
88. **Plaintiff David Sneed** is a United States citizen and a resident of the State of Ohio.
- a. Sneed is currently a death-sentenced inmate in the custody of Defendants.
 - b. Sneed is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #192-040.
 - c. **Plaintiff Sneed has a scheduled execution date of December 9, 2020.**
89. **Plaintiff Dawud Spaulding** is a United States citizen and a resident of the State of Ohio.

- a. Spaulding is currently a death-sentenced inmate in the custody of Defendants.
- b. Spaulding is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #634-998.
- c. Plaintiff Spaulding does not have a scheduled execution date.

90. **Plaintiff Warren Spivey** is a United States citizen and a resident of the State of Ohio.

- a. Spivey is currently a death-sentenced inmate in the custody of Defendants.
- b. Spivey is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #216-212.
- c. Plaintiff Spivey does not have a scheduled execution date.

91. **Plaintiff John David Stumpf** is a United States citizen and a resident of the State of Ohio.

- a. Stumpf is currently a death-sentenced inmate in the custody of Defendants.
- b. Stumpf is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him

incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #181-258.

c. Plaintiff Stumpf has a scheduled execution date of April 16, 2020.

92. **Plaintiff James Trimble** is a United States citizen and a resident of the State of Ohio.

- a. Trimble is currently a death-sentenced inmate in the custody of Defendants.
- b. Trimble is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #494-014.
- c. Plaintiff Trimble does not have a scheduled execution date.

93. **Plaintiff Michael Turner** is a United States citizen and a resident of the State of Ohio.

- a. Turner is currently a death-sentenced inmate in the custody of Defendants.
- b. Turner is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #438-811.
- c. Plaintiff Turner does not have a scheduled execution date.

94. **Plaintiff Raymond Twyford** is a United States citizen and a resident of the State of Ohio.

- a. Twyford is currently a death-sentenced inmate in the custody of Defendants.
- b. Twyford is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #275-069.
- c. Plaintiff Twyford does not have a scheduled execution date.

95. **Plaintiff Robert Van Hook** is a United States citizen and a resident of the State of Ohio.

- a. Van Hook is currently a death-sentenced inmate in the custody of Defendants.
- b. Van Hook is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #186-347.
- c. **Plaintiff Van Hook has a scheduled execution date of July 18, 2018.**

96. **Plaintiff Warren Waddy** is a United States citizen and a resident of the State of Ohio.

- a. Waddy is currently a death-sentenced inmate in the custody of Defendants.

b. Waddy is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #199-737.

c. Plaintiff Waddy does not have a scheduled execution date.

97. **Plaintiff Michael Webb** is a United States citizen and a resident of the State of Ohio.

a. Webb is currently a death-sentenced inmate in the custody of Defendants.

b. Webb is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #246-589.

c. Plaintiff Webb’s execution is stayed and preliminarily enjoined by order of this Court.

98. **Plaintiff James Were** is a United States citizen and a resident of the State of Ohio.

a. Were is currently a death-sentenced inmate in the custody of Defendants.

b. Were is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at Ohio State Penitentiary, 878 Coitsville-Hubbard Road, Youngstown, Ohio, under Inmate #173-245.

- c. Plaintiff Were does not have a scheduled execution date.
99. **Plaintiff Hersie Wesson** is a United States citizen and a resident of the State of Ohio.
- a. Wesson is currently a death-sentenced inmate in the custody of DRC Defendants.
 - b. Wesson is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #563-308.
 - c. Plaintiff Wesson does not have a scheduled execution date.
100. **Plaintiff Andre Williams** is a United States citizen and a resident of the State of Ohio.
- a. Williams is currently a death-sentenced inmate in the custody of Defendants.
 - b. Williams is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #209-534.
 - c. Plaintiff Williams does not have a scheduled execution date.
101. **Plaintiff Clifford Williams** is a United States citizen and a resident of the State of Ohio.
- a. Williams is currently a death-sentenced inmate in the custody of Defendants.

- b. Williams is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #237-994.
- c. Plaintiff Williams does not have a scheduled execution date.

102. **Plaintiff Robert Williams** is a United States citizen and a resident of the State of Ohio.

- a. Williams is currently a death-sentenced inmate in the custody of Defendants.
- b. Williams is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #381-764.
- c. Plaintiff Williams does not have a scheduled execution date.

103. **Plaintiff Jeffrey Wogenstahl** is a United States citizen and a resident of the State of Ohio.

- a. Wogenstahl is currently a death-sentenced inmate in the custody of Defendants.
- b. Wogenstahl is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate #269-357.

c. Plaintiff Wogenstahl has a scheduled execution date of April 17, 2019.

B. Defendants

104. **Defendant John Kasich** is the Governor of the State of Ohio and has been since on or about January 10, 2011. He is the final executive authority in the state, statutorily and constitutionally responsible for the execution of all death sentences in Ohio and the manner in which those sentences are executed. He is sued here in his official capacity for the purpose of obtaining equitable, declaratory and injunctive relief.
105. **Defendant Gary C. Mohr** is the Director of the Ohio Department of Rehabilitation and Corrections (“DRC” or “ODRC”), a department of the State of Ohio that was created and is maintained pursuant to Ohio Revised Code § 5120. DRC Defendants claim that Defendant Mohr is charged with and authorized under Ohio Revised Code § 5120.01 to prescribe and direct the promulgation of rules and regulations for the DRC, including the rules and regulations for the conduct of prison operations and execution procedures. Director Mohr (or his designee) oversees all executions administered in Ohio. He is sued here in his official capacity for the purpose of obtaining equitable, declaratory and injunctive relief.
106. **Defendant Stephen Gray** is Chief Counsel of DRC. Upon information and belief, Defendant Gray has been tasked with creating rules and

regulations for the conduct of prison operations and execution procedures, including the DRC policy designated 01-COM-11. Upon information and belief, Defendant Gray has also been tasked with identifying sources of execution drugs for DRC to use in carrying out a lethal-injection execution and/or obtaining or facilitating DRC's acquisition of execution drugs. He is sued here in his official capacity for the purpose of obtaining equitable, declaratory and injunctive relief.

107. **Defendant Ronald Erdos** is Warden of the Southern Ohio Correctional Facility, a correctional institution of the DRC that was created and is maintained pursuant to Ohio Revised Code § 5120.05. SOCF is the prison where Ohio carries out its death sentences. Pursuant to Ohio Revised Code § 5120.38, Defendant Erdos, as the Warden of SOCF, is charged with management of SOCF and the oversight and conduct of operations at SOCF, including executions carried out there. He is sued here in his official capacity for the purpose of obtaining equitable, declaratory and injunctive relief.
108. **Defendant Donald Morgan** is an individual employed by DRC and, upon information and belief, an individual to whom has been delegated responsibility related to carrying out executions in Ohio. He is sued here in his official capacity for the purpose of obtaining equitable, declaratory and injunctive relief.

109. **Defendant Edwin Voorhies** is a Managing Director of Operations at DRC, and, upon information and belief, an individual to whom has been delegated responsibility related to carrying out executions in Ohio. Defendant Voorhies has also been identified as one to whom the Director delegates command authority as the Director's "designee" for carrying out an execution. He is sued here in his official capacity for the purpose of obtaining equitable, declaratory and injunctive relief.
110. **Defendant Richard Theodore** is a pharmacist employed by DRC and, upon information and belief, an individual to whom has been delegated responsibility for matters related to execution drugs. Except as otherwise designated in specific claims in which he is sued in his individual capacity, he is sued here in his official capacity for the purpose of obtaining equitable, declaratory and injunctive relief.
111. **Defendant Charlotte Jenkins** is the Warden at Chillicothe Correctional Center, a correctional institution of the DRC that was created and is maintained pursuant to Ohio Revised Code § 5120.05. CCI is the prison where Ohio currently houses the majority of its death row inmates, including Plaintiff. Pursuant to Ohio Revised Code § 5120.38, Defendant Jenkins, as the Warden of CCI, is charged with management of CCI and the oversight and conduct of operations at CCI. Pursuant to DRC Policy 01-COM-11, Defendant Jenkins will be responsible for implementing some portions of the Execution

- Protocol before Plaintiff is transferred to SOCF the day before a scheduled execution. She is sued here in her official capacity for the purpose of obtaining equitable, declaratory and injunctive relief.
112. **Defendant John Coleman** is the Warden at Toledo Correctional Institution, a correctional institution of the DRC that was created and is maintained pursuant to Ohio Revised Code § 5120.05. ToCI is the prison where, upon information and belief, Ohio houses or will soon house the majority of its death row inmates, including Plaintiff. Pursuant to Ohio Revised Code § 5120.38, Defendant Coleman, as the Warden of ToCI, is charged with management of ToCI and the oversight and conduct of operations at TCI. Pursuant to DRC Policy 01-COM-11, Defendant Coleman will be responsible for implementing some portions of the Execution Protocol before an inmate housed at ToCI is transferred to SOCF the day before a scheduled execution. He is sued here in his official capacity for the purpose of obtaining equitable, declaratory and injunctive relief.
113. **Defendants unnamed and anonymous execution team members** are individuals involved with administering Defendants' execution protocol, policies and procedures, and who are known to Defendants and have been previously identified by court order only by anonymous team member numbers. The Execution Team Members are sued in their official capacities for the purpose of obtaining equitable, declaratory and injunctive relief.

114. For ease of reference herein, Defendants Kasich, Mohr, Gray, Morgan, Voorhies, Theodore, Jenkins, Coleman, unnamed and anonymous execution team members, and their predecessors (including Strickland, Collins, Trout, Morgan, Kerns, and former execution team members) are hereinafter called the "**DRC Defendants.**"
115. Each of the DRC Defendants, at all times relevant hereto, are acting in their respective official capacities and under the color and authority of state law with respect to all acts described herein.
116. **Defendants Unknown Pharmacies #1-100** are partnerships, corporations or other business entities organized and existing under the laws of the State of Ohio, or some other state of the United States of America, or some foreign jurisdiction, that are in the business of practice of pharmacy, and that are assisting DRC, either directly or through intermediaries, with obtaining drugs for the purposes of carrying out executions by lethal injection.
117. Plaintiff cannot discover the names of Defendants Unknown Pharmacies #1-100 because their identity and location are unknown at this time. Plaintiff is informed and has reason to believe that Defendants Unknown Pharmacies #1-100 are legally responsible, negligently or in some other actionable manner, for the events and occurrences described in this Fourth Amended Omnibus Complaint. The true names and capacities of Defendants Unknown Pharmacies #1-100 are unknown to Plaintiff at this time, although they are

known to one or more DRC Defendants, and Plaintiff has, therefore, sued these unknown Defendants under fictitious names. When the true names and capacities of the Defendants Unknown Pharmacies #1–100 have been ascertained, Plaintiff will seek leave to amend this Fourth Amended Omnibus Complaint accordingly. Defendants Unknown Pharmacies # 1–100 are private persons or entities who are acting under the color of law, and they are sued for the purpose of obtaining equitable, declaratory and injunctive relief.

118. **Defendants Pharmacists #1–100** are individuals engaged in the practice of pharmacy and that are assisting DRC, either directly or through intermediaries, with obtaining drugs for the purposes of carrying out executions by lethal injection. Plaintiff cannot discover the names of Defendants Unknown Pharmacists #1–100 because their identity and location are unknown at this time. Plaintiff is informed and has reason to believe that Defendants Unknown Pharmacists #1–100 are legally responsible, negligently or in some other actionable manner, for the events and occurrences described in this Fourth Amended Omnibus Complaint. The true names and capacities of Defendants Unknown Pharmacists #1–100 are unknown to Plaintiff at this time, although they are known to one or more DRC Defendants, and Plaintiff has, therefore, sued these unknown Defendants under fictitious names. When the true names and capacities of the Defendants Unknown Pharmacists #1–100 have been ascertained,

Plaintiff will seek leave to amend this Fourth Amended Omnibus Complaint accordingly. Defendants Unknown Pharmacists #1–100 are private persons who are acting under the color of law, and they are sued for the purpose of obtaining equitable, declaratory and injunctive relief.

119. **Defendants Drug Suppliers #1–25** are individuals, partnerships, corporations or other business entities organized and existing under the laws of the State of Ohio, or some other state of the United States of America, or some foreign jurisdiction, engaged in manufacturing, procurement, transportation, import, export, sale (either retail or wholesale), supplying, or other distribution of drugs and that are assisting DRC, either directly or through intermediaries, with obtaining drugs for the purposes of carrying out executions by lethal injection.
120. Plaintiff cannot discover the names of Defendants Drug Suppliers #1–25 because their identity and location are unknown at this time. Plaintiff is informed and has reason to believe that Defendants Drug Suppliers #1–25 are legally responsible, negligently or in some other actionable manner, for the events and occurrences described in this Fourth Amended Omnibus Complaint. The true names and capacities of Defendants Drug Suppliers #1–25 are unknown to Plaintiff at this time, although they are known to one or more DRC Defendants, and Plaintiff has, therefore, sued these unknown Defendants under

- fictitious names. When the true names and capacities of the Defendants Drug Suppliers #1–25 have been ascertained, Plaintiff will seek leave to amend this Fourth Amended Omnibus Complaint accordingly. Defendants Drug Suppliers # 1–25 are private persons or entities who are acting under the color of law, and they are sued for the purpose of obtaining equitable, declaratory and injunctive relief.
121. **Defendants John Does # 1–25** are individuals who are employed by or are associated with those Defendants Pharmacies #1–100 or Defendants Drug Suppliers # 1–25 who are not individuals. The true names and capacities of Defendants John Does # 1–25 are unknown to Plaintiff at this time, and Plaintiff has, therefore, sued these unknown Defendants under fictitious names. When the true names and capacities of the Defendants John Does # 1–25 have been ascertained, Plaintiff will seek leave to amend this Fourth Amended Omnibus Complaint accordingly.
122. For ease of reference herein, Defendants Pharmacies #1–100, Compounding Pharmacists #1–100, Drug Suppliers # 1–25, and Defendants John Does # 1–25 are hereinafter collectively called the **“Drug Source Defendants”** unless otherwise noted.
123. Each of the Drug Source Defendants, at all times relevant hereto, are acting under the color and authority of state law.
124. The DRC Defendants and the Drug Source Defendants are hereinafter collectively called **“Defendants.”**

125. Upon information and belief, unless preliminarily and permanently enjoined, each of Defendants intends to act in their respective capacities and under the color and authority of state law to facilitate the execution of Plaintiff.

EXHAUSTION OF ADMINISTRATIVE REMEDIES

126. Pursuant to the Joint Stipulation filed on August 25, 2011 (*Cooey v. Kasich*, S.D. Ohio Case No. 04-1156, ECF No. 971), any exhaustion defenses have been affirmatively and explicitly waived.

JUSTICIALE CASE OR CONTROVERSY

127. There is a real and justiciable case or controversy between the parties.

128. The DRC Defendants have promulgated their formal execution protocol as DRC Policy 01-COM-11, and they have adopted informal execution policies and procedures as well. The version of the DRC Defendants' formal execution protocol that is effective as of the filing of this Fourth Amended Omnibus Complaint was adopted effective October 7, 2016, and is hereinafter called "the 2016 Execution Protocol" or the "Execution Protocol."

129. Upon information and belief, if Plaintiff's capital conviction or death sentence is not overturned in another judicial proceeding or through executive clemency, then Defendants will attempt to execute him.

130. It is the intention of Defendants, acting in concert and acting in concert with other state officials not named as defendants herein, to

execute Plaintiff in the death house located on the grounds of the Southern Ohio Correctional Facility (“SOCF”) in Lucasville, Ohio, which is operated and controlled by the DRC Defendants.

131. Absent judicial intervention, Plaintiff will be executed pursuant to Defendants’ arbitrary and capricious lethal injection protocol, policies and procedures. There is a justiciable case or controversy regarding the unconstitutionality of Defendants’ execution protocol, policies and procedures.
132. Plaintiff challenges the constitutionality of Defendants’ lethal injection execution protocol and policies under 42 U.S.C. § 1983. This lawsuit does not challenge the fact of his conviction or his death sentence.

RELEVANT FACTS

133. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Fourth Amended Omnibus Complaint as if fully stated herein.
134. Plaintiff is alleging constitutional violations based on Defendants’ current Execution Protocol effective October 7, 2016; he is not alleging that Defendants can never execute him by any method.
135. Defendants have created, maintained and implemented a lethal injection execution policy which includes the Execution Protocol and the administration of said written protocol and Defendants’ informal policies, by which they intend to execute Plaintiff.

136. Defendants' execution policy and written Execution Protocol manifests Defendants' deliberate indifference towards Plaintiff's constitutional rights. The execution policy and Execution Protocol, as written and as applied, violate Plaintiff's constitutional rights to be free from cruel and unusual punishment which rights are secured and guaranteed to him by the Eighth and Fourteenth Amendments' limitations on Defendants' powers while acting individually or under the color and authority of state law, and/or does not protect against or prevent Defendants from conducting an unconstitutional execution because of the lack of necessary procedural safeguards.
137. Defendants' execution policy and written Execution Protocol must contain procedural safeguards critical to ensuring against Eighth Amendment violations, and those safeguards must be followed.
138. Plan 1 of DRC Defendants' Execution Protocol requires the peripheral intravenous injection, via two syringes of 2.5 grams each of pentobarbital, for a total of 5 grams of pentobarbital.
139. Plan 2 of DRC Defendants' Execution Protocol requires the peripheral intravenous injection, via five syringes, of five grams of thiopental sodium.
140. Plan 3 of DRC Defendants' Execution Protocol requires the peripheral intravenous injection, via two syringes, of 500 milligrams of midazolam hydrochloride, followed by injection, via two syringes, of a

paralytic drug, followed by injection, via two syringes, of 240 milliequivalents of potassium chloride.

141. In the October 7, 2016 Execution Protocol, Defendants for the first time omitted any required concentration of the execution drugs.
142. Plan 1 and Plan 2 and Plan 3 of the Execution Protocol and Defendants' unwritten practices violate Plaintiff's rights under the Eighth and Fourteenth Amendments.
143. By adhering to Plan 1 or Plan 2 or Plan 3 of the Execution Protocol, Defendants will violate the Eighth and Fourteenth Amendments to the United States Constitution and 42 U.S.C. § 1983.
144. In accordance with Plaintiff's allegations related to imported execution drugs, the use of imported drugs in executions is sure or very likely to cause serious harm, including severe physical and mental pain and torturous suffering, a lingering death, an undignified, spectacle execution, and being subjected to an impermissible, unwanted, non-consensual human experimentation during Plaintiff's execution.
145. In accordance with Plaintiff's allegations related to compounded execution drugs, the use of compounded drugs in executions is sure or very likely to cause serious harm, including severe physical and mental pain and torturous suffering, a lingering death, an undignified, spectacle execution, and being subjected to an impermissible, unwanted, non-consensual human experimentation during Plaintiff's execution.

146. An execution procedure that causes death by suffocation while the condemned inmate is conscious, or aware of or sensate to what he is experiencing violates the Eighth and Fourteenth Amendments to the Constitution of the United States.
147. An execution procedure that causes death by heart attack while the condemned inmate is conscious, or aware of or sensate to what he is experiencing violates the Eighth and Fourteenth Amendments to the Constitution of the United States.
148. An execution procedure that is sure or very likely to cause psychologically or mentally torturous pain, agony and suffering violates the Eighth and Fourteenth Amendments to the Constitution of the United States.
149. An execution procedure that is sure or very likely to cause a lingering death violates the Eighth and Fourteenth Amendments to the Constitution of the United States. *In re Kemmler*, 136 U.S. 436, 447 (1890); *see also Baze v. Rees*, 553 U.S. 35, 100 (2008) (Thomas, J. concurring).
150. An execution procedure that Defendants use with the purpose of causing severe physical pain or horrific mental suffering and anguish violates the Eighth and Fourteenth Amendments to the Constitution of the United States.
151. An execution procedure that Defendants use with the knowledge that it will cause needless, severe physical pain or horrific mental suffering

- and anguish violates the Eighth and Fourteenth Amendments to the Constitution of the United States. *Farmer v. Brennan*, 511 U.S. 825, 836–40 (1994); *Wilkerson v. Utah*, 99 U.S. 130, 136 (1879); *In re Kemmler*, 136 U.S. 436, 447 (1890).
152. An execution procedure that is sure or very likely to cause an undignified death or a spectacle of an execution violates the Eighth and Fourteenth Amendments to the Constitution of the United States.
153. An execution procedure that is sure or very likely to subject a condemned inmate to an impermissible experimental execution that is arbitrary and capricious violates the Eighth and Fourteenth Amendments to the Constitution of the United States.
154. An execution procedure that is sure or very likely to subject a condemned inmate to maladministration or arbitrary and capricious administration of the execution protocol violates the Eighth and Fourteenth Amendments to the Constitution of the United States.
155. An execution procedure that does not include sufficient safeguards or mechanisms in the execution policy or the Execution Protocol to prevent execution of a condemned inmate who is categorically barred from execution because he is intellectually disabled or incompetent to be executed creates a substantial risk that an ineligible person will be executed, and therefore facially violates the Eighth and Fourteenth Amendments to the Constitution of the United States.

156. Plaintiff is scheduled for execution because he was convicted of aggravated murder. He greatly fears that any Drug Source Defendants who participate in his execution, in addition to lacking required skill and competence, will be unable to ignore the magnitude of Plaintiff's crime and will allow such considerations to subvert the work product.
157. These fears are magnified many times over because the DRC Defendants have omitted any significant oversight, redundancies, and other reviews and checks of the work product, the manufacturing facilities, manufacturing protocols and other key facets of the drug manufacturing or compounding process used by the Drug Source Defendants.
158. The DRC Defendants' allowance of so much unchecked power over the execution process to reside with unknown Drug Source Defendants is unconscionable, exposes as illusory the DRC Defendants' purported procedural protections and repeated assurances of a commitment to an execution process that is humane and protective against human error, and is violative of Plaintiff's constitutional and statutory rights.
159. The existence of the known, foreseeable and objectively intolerable risks identified in Plaintiff's Complaint further substantially increases the likelihood that Plaintiff will be exposed to severe harm during his execution, all to his extreme prejudice and in violation of his constitutional and statutory rights.

160. In all the ways alleged in the Causes of Action asserted below, Defendants' execution policy and written Execution Protocol subject Plaintiff to violations of his constitutional rights. The Execution Protocol is unconstitutional, facially and as applied to Plaintiff.

A. Historical background of Ohio's execution protocol and its adoption of the current Execution Protocol.

161. At all times from 1994 to present, Ohio's statute governing lethal

injection mandated that Defendants conduct a lethal injection

execution such that it produces a "quick and painless" death. Ohio

Rev. Code § 2949.22(A).

162. DRC Defendants have changed the execution protocol repeatedly since 1994.

163. The DRC Defendants' adoption of the 2016 Execution Protocol

restarts any applicable statute of limitations for associated

constitutional challenges.

164. DRC Defendants' inclusion of compounded execution drugs as an

option under the Execution Protocol is not simply a matter of

swapping out one execution drug source for another. Involvement of

compounded execution drugs directly involves a health care

practitioner and the laws that govern that health care practitioner's

behavior.

165. At all times relevant hereto, Ohio Revised Code § 2108.40 provided

the legal definition of "death" under Ohio law: "An individual is dead if

the individual has sustained either irreversible cessation of circulatory

and respiratory functions or irreversible cessation of all functions of the brain, including the brain stem, as determined in accordance with accepted medical standards.”

166. By changing their execution protocol with great frequency, by using drugs or combinations of drugs and doses that are unsupported by any scientific studies or data, by contemplating the use of compounded execution drugs or unapproved drugs illegally imported from unreliable foreign manufacturers, and by resurrecting the revised three-drug method using midazolam as the experimental first drug of a three-drug procedure, Defendants are conducting experimental executions on each condemned inmate.
167. DRC Defendants have designated DRC Policy 01-COM-11 as the DRC policy controlling human executions in Ohio.
168. Policy 01-COM-11 carries the force of Ohio administrative law.
169. Policy 01-COM-11 requires that all execution processes must be performed in a professional, humane, sensitive, and dignified manner.
170. Policy 01-COM-11 requires that the Execution Protocol must be applied in accordance with all applicable policies, administrative regulations, and statutes.
171. Since 1994, DRC Defendants have adopted a number of superseding written rules and policies as their execution protocol, originally designated as rule 001-09, and then designed DRC Policy 01-COM-11. Versions of rule 001-09 were adopted as effective on the following

- dates: March 30, 1994; April 12, 2001; August 21, 2001; September 11, 2001; November 21, 2001; and July 17, 2003.
172. Versions of DRC Policy 01-COM-11 were adopted as effective on the following dates: January 8, 2004; July 10, 2006; October 11, 2006; May 14, 2009; November 30, 2009; November 15, 2010; March 9, 2011; April 11, 2011; September 18, 2011; October 10, 2013; April 28, 2014; January 9, 2015; June 29, 2015; and October 7, 2016.
173. The three drugs to be used under Plan 3 of the October 7, 2016 protocol, administered in order of succession, are: (1) midazolam hydrochloride, a drug in the benzodiazepine class (hereinafter “midazolam”); (2) a paralytic drug; and (3) potassium chloride.
174. In addition to this three-drug execution method, the Execution Protocol also provides that executions by lethal injection may be carried out using the one-drug barbiturate-only method, with either pentobarbital or sodium thiopental as the barbiturate.
175. At the quantities used in the three-drug method, both the paralytic drug and the potassium chloride are excruciatingly painful drugs.
176. When administered intravenously through IV catheters in peripheral veins, these drugs inflict extreme, searing pain throughout the entire time they travel through the circulatory system and into the lungs and heart.

177. The paralytic drug suppresses breathing, but does not hasten the death subsequently caused by potassium chloride, nor does it protect against the inmate's pain.
178. The potassium chloride, once it reaches the heart, disrupts the heart's electrical activity, causing excruciatingly painful cardiac arrest and death.
179. The experience of enduring IV-administered, execution-level doses of these two drugs is as, or more painful than, enduring a major surgical procedure while awake, conscious, aware and sensate to pain, without General Anesthesia, and while paralyzed layered with the additional pain of suffering sudden cardiac arrest.
180. Unless the inmate is effectively rendered unconscious, unaware and insensate (unable to experience and feel pain) akin to being in a state of General Anesthesia before any injection of the paralytic drug and potassium chloride, and unless that level of unconsciousness, unawareness and insensate state is maintained until death, it is sure or very likely that the inmate will experience and suffer through the excruciatingly painful effects of the paralytic drug and potassium chloride, throughout the course of administration of these drugs, until death.
181. Rendering and maintaining a person unconscious, unaware and insensate to severe pain using midazolam is virtually impossible at any dose, and would require involvement of persons with the proper

training, using proper monitoring equipment, and who have the requisite experience, judgment, and skill to do so.

182. The difficulty of delivering and maintaining unconsciousness, unawareness, and insensation akin to General Anesthesia with midazolam as the first of a three-drug method is increased by the fact that the execution drugs are not injected directly into the inmate at bedside, but rather are delivered intravenously, through the same peripheral IV line, without any high pressure saline flush afterwards, through 10 to 15 feet of IV tubing that originates in a different room from where the inmate is being executed.
183. The execution team members administering the execution drugs are thus not with the inmate at the execution gurney, but instead are some 10 to 15 feet away in another room, and observing only through tinted glass.
184. The difficulty of ensuring the condemned inmate is unconscious, unaware and insensate to severe pain during injection of the second and third drugs is further increased by the fact that the paralytic drug renders completely unavailable one of the most reliable means for determining that a person is not unconscious, unaware, and insensate to severe pain: the purposeful bodily movements, sounds, and facial expressions of the inmate that would be observed absent the artificial chemical curtain.

185. Determining that the condemned inmate is tearing from the eyelids, sweating, has an elevated heart rate, or a change in frequency of brain waves, using the appropriate monitoring equipment, would be a way to establish the inmate is conscious, aware, or sensate to severe pain.
186. Because the paralytic drug has the effect of paralyzing all voluntary muscles in the body, the inmate is physically unable to show signs of consciousness, pain or awareness, such as screaming, wincing or other facial expressions, productive tearing from his eyes, or any other responsive movements or actions to express his internal distress.
187. The paralytic drug thus serves a pernicious purpose—to mask the searing pain caused by injection of the second and third drugs, the horrifying sensation of suffocation caused by the paralytic itself, the painful effects of the potassium chloride causing a heart attack, and the pain and suffering associated with dying from those drugs in a lethal injection.
188. In effect, the paralytic drug serves simply to hide relevant evidence, masking whether the first drug is in fact effective in preventing the inmate from suffering the unconstitutional, intense pain caused by both the heart-stopping drug and the paralytic itself.
189. Defendants do not employ any technological assessment tools to determine whether the condemned inmate is unconscious, unaware, and insensate to severe pain at the point where they begin the injections of the paralytic drug. Such assessment tools would include

- blood pressure cuffs, EKG's that monitor electrical activity in the heart, and EEG monitors, such as a BIS monitor, that provide data from which to assess whether a person is conscious, or aware, or otherwise able to feel and experience noxious stimuli such as severe pain.
190. Defendants are able to obtain such technological assessment tools with ordinary transactional effort, and they are trained to properly use those tools or could be easily trained to do so.
191. But Defendants refuse to use any technological assessments of the condemned inmate's consciousness, awareness and sensation to severe pain.
192. Assessing the inmate's level of consciousness, awareness, and sensation to severe pain is critical in the execution context, to avoid subjecting the inmate to certain, unconstitutional severe pain and torturous suffering from the second and third drugs and the process of dying from those drugs.
193. Instead, Defendants employ paramedical techniques that are only appropriately used in emergency situations in which saving the life of the subject—not protecting them from unconstitutional infliction of severe pain and suffering—is the paramount concern, secondary to whether the person will feel excruciating pain from the emergency procedures conducted on him or her.

194. Defendants use “consciousness checks” which are, in reality, nothing more than assessments of reflexive responses. While the presence of purposive responses to reflex checks is evidence of consciousness, awareness, or sensation to severe pain, the absence of reflexive response to such checks does *not* establish evidence of unconsciousness, unawareness, and insensation to severe pain and suffering.
195. An execution protocol that employs midazolam as the first of a three-drug protocol to be followed by a paralytic agent and then potassium chloride, administered through approximately 10-15 feet of IV tubing, in a rapid pace such that the paralytic agent is injected only a matter of approximately a minute to 90 seconds after the syringes of midazolam are fully injected, with rudimentary reflex checks instead of genuine and reliable assessments of consciousness, awareness, and sensation to severe pain and suffering that technological monitoring would provide, makes it sure or very likely that an inmate will be conscious, aware, and sensate to experience the severe pain and horrific suffering associated with the second and third drugs and the process of dying from injection of those drugs.
196. Allegations regarding specific executions in which problems are known to have occurred (under DRC Defendants’ execution protocols or using the same or similar protocols in other jurisdictions) are made in Section O below. Upon information and belief, the problems were

much more frequent than Plaintiffs in this litigation have been able to uncover to this point.

197. On June 10, 2008, an Ohio state trial court held that the use of a three-drug lethal injection protocol, and particularly the use of a paralytic drug and potassium chloride, is “inconsistent with the intent of the General Assembly in enacting R.C. § 2949.22 and violates the duty of the Department of Rehabilitation and Correction, mandated by R.C. § 2949.22, to ensure the statutory right of the condemned person to an execution without pain, and to an expectancy that his execution will be painless.” *State v. Rivera*, Case No. 04CR065940, Judgment Entry (Lorain C.P. June 10, 2008).
198. DRC Defendants’ decision to resurrect the three-drug method with its use of the paralytic drug and potassium chloride, after they had abandoned that method and those drugs in 2009, and used a one-drug, barbiturate-only execution method for several years increases the risk of severe pain to which the condemned inmate is subjected.

B. Allegations regarding Drug Source Defendants’ status as acting under color of law.

199. Plaintiff is informed and has reason to believe that Drug Source Defendants will act in concert with the DRC Defendants to carry out the mission-critical—but prohibited by law—task of procuring and supplying controlled substances to the DRC Defendants to carry out one or more executions.

200. Plaintiff is informed and has reason to believe that Drug Source Defendants are legally responsible, negligently or in some other actionable manner, for the events and occurrences described in this Fourth Amended Omnibus Complaint.
201. The Execution Protocol allows several different DRC Defendants or their agents to order and obtain execution drug(s) from the Ohio Pharmacy Services of the Ohio Department of Mental Health and Addiction Services, a pharmacy, manufacturer, supplier, wholesaler, or distributor, or from any other licensed pharmacist.
202. The Execution Protocol does not expressly require—but implicitly requires—that the DRC Defendants obtain the execution drugs from a pharmacy, manufacturer, supplier, distributor, wholesaler, pharmacist, or compounding pharmacy that is a legally operating business entity located within Ohio (or even within the United States) with all required federal and Ohio licenses and up-to-date regulatory inspections.
203. The Execution Protocol does not expressly require—but implicitly requires—that the DRC Defendants obtain the execution drugs from a pharmacist or compounding pharmacy licensed in Ohio (or even within the United States).
204. The Execution Protocol does not expressly limit—but implicitly limits—the source of execution drugs to an Ohio-licensed pharmacist

working in the scope of his or her employment at an Ohio-licensed pharmacy or compounding pharmacy.

205. The DRC Defendants have now elected to involve, and, upon information and belief, are now recruiting or have already successfully recruited, one or more persons or entities—to wit, the Drug Source Defendants—who are appropriately described under the Execution Protocol as Support Staff because they have a specified role in the Execution Protocol—to provide the execution drugs.
206. Upon information and belief, the DRC Defendants have elected to obtain or to seek to obtain execution drug(s) from any number of the Drug Source Defendants.
207. Upon information and belief, Defendants plan to use or will use execution drug(s) for Plaintiff's execution that have been manufactured via compounding, or manufactured overseas and then imported into the United States, or supplied, distributed or otherwise provided to DRC Defendants by Drug Source Defendants.
208. Carrying out a state-sanctioned execution in Ohio has historically been a power reserved to the State. Likewise, procuring and providing to DRC drugs to use for a lethal-injection execution in Ohio has historically been a function performed exclusively by a State agency, to wit, the Ohio Department of Mental Health and Addiction Services (or its predecessor) and that agency's operations previously known as Central Pharmacy-Inpatient.

209. The Drug Source Defendants are willful, joint—and indeed, indispensable—participants in overt actions with the DRC Defendants necessary to carry out an execution in Ohio, with a substantial degree of cooperation between the Drug Source Defendants and the DRC Defendants, solemnized by contract, to create or otherwise provide to DRC Defendants execution drugs and use them in an execution in violation of numerous state, federal and constitutional provisions.
210. Recent amendments to the Ohio Revised Code confirm that Drug Source Defendants are considered by the State of Ohio to be “necessary” to the State’s efforts to carrying out a lethal-injection execution, with virtually no difference in the eyes of the State of Ohio between DRC Defendants and Drug Source Defendants insofar as their respective necessity to carrying out an execution.
211. Ohio Revised Code § 2949.221, by intentionally blurring into nonexistence any distinction between Drug Source Defendants and DRC Defendants for purposes of carrying out a lethal-injection execution, unambiguously establishes that Drug Source Defendants are state actors acting under color of law.
212. Section 7(C) of the legislative enactment that adopted § 2949.221 (*i.e.*, HB 663, effective March 23, 2015) stated that the intent of the General Assembly in enacting § 2949.221 and related provisions of HB 663 is “to enable [DRC] to obtain the necessary assistance of persons in carrying out a court-ordered sentence of death by lethal

injection or the drugs needed to administer such a sentence," by which was meant specifically the assistance of private persons and entities such as the Drug Source Defendants.

213. Upon information and belief, the Drug Source Defendants, by compounding, manufacturing, importing, or otherwise supplying execution drugs to the DRC Defendants to use in a state-administered execution, are performing and have assumed a function that was traditionally reserved to the State and performed by a public agency.
214. Because manufacturing, compounding, distributing, dispensing, introducing into interstate commerce, selling, delivering, holding or offering for sale, importing, and other actions related to the drugs identified in the Execution Protocol to be used as execution drugs are prohibited by numerous provisions of federal and state law, the Drug Source Defendants, by contracting or otherwise working with DRC Defendants, are jointly and willfully engaged with State officials in prohibited actions, and are thus acting under color of law.
215. Upon information and belief, Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 and others of the Drug Source Defendants have contracted or otherwise agreed to work with DRC Defendants specifically for the purpose of providing specialized pharmaceutical services in the form of compounded drugs to be used for a lethal-injection execution, including for the planned execution of Plaintiff.

216. Upon information and belief, Drug Source Defendants have contracted or otherwise agreed to work with DRC Defendants specifically for the purpose of providing services in the form of procuring any of the drugs in the Execution Protocol manufactured overseas and imported into the United States to be used for a lethal-injection execution, including for the planned execution of Plaintiff.
217. The Drug Source Defendants are or will be aware of the purpose and intent for which they will specifically manufacture, compound, supply, distribute or otherwise provide the execution drug(s) sought by the DRC Defendants, namely the execution of one or more readily identifiable condemned inmates scheduled for execution on a particular date at a particular time for a particular crime.
218. The Execution Protocol's delegation of a critical element of the execution process—manufacturing, compounding, importing, distributing or otherwise supplying the execution drug(s), to be used solely for executions on a known date and time and for a known inmate or inmates—to the Drug Source Defendants vests tremendous responsibility and authority in the Drug Source Defendants.
219. Upon information and belief, the DRC Defendants have never before vested such tremendous responsibility and authority in any such unknown private parties with respect to the execution process, and certainly not since Ohio began conducting executions by lethal injections in 1999.

C. Allegations related to the requirements of DRC Defendants' Execution Protocol.

220. In all respects relevant to the infliction of needless severe pain and suffering, Defendants' current three-drug method is a substantially riskier and more dangerous three-drug method than the original three-drug method Defendants previously employed before November 30, 2009.
221. DRC Defendants knowingly, intentionally and purposefully reintroduced the needless, unacceptable harm of the paralytic drug and potassium chloride, which are sure or likely to cause severe pain to the condemned inmate who is conscious, aware, or at least sensate, into the execution protocol again when they adopted the current Execution Protocol.
222. Moreover, DRC Defendants have knowingly, intentionally and purposefully reintroduced the needless, unacceptable harm of midazolam in the execution protocol.
223. Thus, not only have DRC Defendants resurrected a method they abandoned in part because there were much more humane options available, but they have now made changes to that abandoned method that make it even worse.
224. Administration of the Execution Protocol to a particular condemned inmate, like with other recent versions of 01-COM-11, begins approximately thirty days in advance of the scheduled execution date.

225. The Execution Protocol contains five Core Elements. Deviation or variation from any of those five Core Elements throughout Defendants' administration of 01-COM-11 to a particular inmate is prohibited by the terms of the Protocol itself, as well as by prior rulings in this litigation.
226. The core elements of the Execution Protocol (hereinafter the "Core Elements") read as follows:
1. At least three Medical Team Members, two of whom are authorized to administer drugs under Ohio law, shall be used in the conduct of court-ordered executions.
 2. The drugs required by this policy shall be used.
 3. Functions required to be performed by medically-qualified persons, as described in this policy, shall be performed by Medical Team Members.
 4. All Execution Team functions shall be performed by appropriately trained and qualified members of the Execution Team.
 5. Only the Director can authorize a variation from the procedures stated in this policy but not a variation from the four requirements listed immediately above in subsection V.1.2.3. and 4. of this policy.
227. The Core Elements purport to provide necessary, core constitutional protections which, among other things, purport to ensure that competent and properly trained actors are involved in key aspects of the execution process and that the respective tasks performed by those actors in these key respects are subject to oversight,

redundancies, and other built-in checks to eliminate mistakes and variations or deviations from the Protocol's protections.

228. Strict compliance with the Core Elements is necessary for Defendants to carry out an execution that adequately protects the condemned inmate's constitutional rights.
229. An execution that is not administered in strict compliance with the Core Elements will subject Plaintiff to violations of his constitutional rights and is unconstitutional.
230. Under Defendants' overarching execution policy and the Execution Protocol, and regardless of the lethal drug(s) to be used, a condemned inmate will be forced to lie down flat on his or her back for periods of time.
231. Upon entering the execution chamber, a condemned inmate will be strapped to the execution bed flat on his or her back, unable to move, with arms outstretched at each side.
232. The DRC Defendants will immobilize the condemned inmate by strapping him or her to the execution bed before the execution team begins attempted insertion of the peripheral IV catheters.
233. The DRC Defendants ensure that a condemned inmate lies flat on his or her back by employing "security team" members surrounding the inmate during efforts to establish IV access, and by strapping the inmate to the execution bed.

234. These security team and/or strap-down team members will physically ensure that an inmate remains flat on his back in a horizontal position throughout these procedures.
235. Although the DRC Defendants purportedly take only one to three minutes to establish peripheral IV access during execution rehearsals, successfully achieving peripheral IV access under the pressure and circumstances of a genuine execution has taken in the past and, upon information and belief, will take in the future, at least several minutes and may take half an hour or substantially more.
236. In the case of DRC Defendants' attempt to execute Romell Broom, some or all of the same DRC Defendant-medical team members who are expected to be on duty for Plaintiff's attempted execution, were unable to successfully achieve and maintain peripheral IV access even after some two hours of trying.
237. During DRC Defendants' execution of Kenneth Biros, it took approximately 30 minutes for DRC Defendants to obtain peripheral IV access.
238. In the execution of Harry Mitts, Jr., the DRC Defendants required at least thirteen minutes to obtain peripheral IV access.
239. In the execution of Dennis McGuire, the DRC Defendants required at least ten minutes to obtain peripheral IV access.
240. In the execution of Gary Otte, the DRC Defendants required approximately ten minutes to obtain peripheral IV access.

241. Under DRC Defendants' overarching execution policy and the Execution Protocol, DRC Defendants will fill the IV tubing running from the equipment room to the inmate's IV catheter with saline solution before injecting the execution drug(s).
242. Under DRC Defendants' overarching execution policy and the Execution Protocol, DRC Defendants will inject the execution drug(s) into the IV tubing in the equipment room that is filled with saline solution. Thereafter a low-pressure saline drip will be used to purportedly "flush" the contents of the IV lines into the inmate.
243. The physical structures of DRC Defendants' execution chamber and the Equipment Room result in an extended length of IV tubing being used to inject the execution drug(s), rather than a bedside injection.
244. Furthermore, that IV tubing will have a dip in the lines similar to an "s-trap" used in plumbing household sinks, in which some amount of the execution drug(s), including the critical first drug in an execution using Plan 3's three-drug method, will be trapped for some period of time during an execution, if not for the duration.
245. Because of the volume of drugs involved, the varying viscosity of the drugs and the saline solution, the length of the IV tubing and the traps in the IV lines, the execution drug(s) will be mixed with the saline solution already in the IV tubing and the saline solution dripped into the lines after the plunger on Syringe 1 is emptied, before it reaches the condemned inmate.

246. For the same reasons, some amount of each of the execution drugs in a three-drug execution method using Plan 3 will remain trapped in the IV lines, mixed with the saline solution and the other drugs injected into the lines.
247. Thus, DRC Defendants will be injecting the execution drug(s) into the condemned inmate at an inconsistent rate other than constant and reliable injection, and the drug(s) that the inmate will receive will be diluted by the saline solution.
248. Because of these factors, it is substantially unlikely that an inmate subjected to Plan 3 of Defendants' execution protocol will actually receive the full amount of midazolam injected into the lines by the time Defendants commence injecting the paralytic, and that some amount of midazolam will remain trapped in the IV lines commingled with saline solution and amounts of the second and third drugs.
249. Under accepted medical standards (Ohio Rev. Code § 2108.40), a simple absence of heart and lung sounds—which is all DRC Defendants assess—does not amount to irreversible cessation of circulatory and respiratory functions, or to irreversible cessation of all functions of the brain, including the brain stem.
250. Under accepted medical standards, visual monitoring and a stethoscope assessment of heart and lung sounds—which is all DRC Defendants do—is insufficient to determine whether an individual has

sustained irreversible cessation of circulatory and breathing functions.

251. Under accepted medical standards, visual monitoring and a stethoscope assessment of heart and lung sounds—which is all DRC Defendants do—is insufficient to determine whether an individual has sustained irreversible cessation of all functions of the brain, including the brain stem.
252. DRC Defendants use only visual observations of the prisoner and a check of heart and lung sounds by stethoscope to declare death. DRC Defendants do not use any other monitoring instruments, devices, or methods that are necessary to determine death “in accordance with accepted medical standards” and Ohio law, Ohio Revised Code § 2108.40.
253. DRC Defendants are unable to declare death in accordance with Ohio law simply by watching the prisoner, or by listening for heart and lung sounds with a stethoscope.
254. Notwithstanding the events that occurred during previous problematic executions in Ohio and in other states, under their Execution Protocol and informal execution policies established by practice and custom, Defendants still do not do any of the following related to a lethal injection execution:
 - use any vital-signs monitoring;
 - use pulse-oximetry (pulse-ox) monitoring;

- have supplies of oxygen on hand in the Death House;
 - have resuscitative drugs, such as the reversal agent or antidote called flumazenil for midazolam, sugammadex for rocuronium bromide and an acetylcholinesterase inhibitor for vecuronium bromide and pancuronium bromide, on hand in the Death House;
 - have ventilation equipment such as ventilation bag, valve and mask, on hand in the Death House;
 - have intubation equipment on hand in the Death House;
 - have any way to maintain a patent (uncompromised) airway and support of ventilation;
 - have any way to prepare and transport an inmate to an emergency health-care provider facility;
 - have any other resuscitative measures readily available and employable in the event that a problem arises during an execution or in the event that a stay of execution is issued after injection of the execution drugs;
 - train for any scenarios under which resuscitative measures would be necessary, or have any resuscitative plan of action at all.
255. If DRC Defendants attempt to execute him, Plaintiff intends to make a last statement before any such attempted execution.
256. DRC Defendants' overarching execution policy and the Execution Protocol lack any restraint on the number of attempts at peripheral IV access or the length of time those pokes, sticks, and stabs to the inmate can persist.
257. DRC Defendants are willing to engage in multiple, lengthy attempts at establishing and sustaining peripheral IV access.
258. DRC Defendants' policy and belief is that they are permitted to engage in efforts to complete an execution from the time the Warden reads

- the death warrant up to midnight of the same day, when the death warrant expires.
259. DRC Defendants' failure to have a time limit for attempting peripheral IV access places the team members in an increasingly stressful situation, rendering the team members unable to constitutionally administer an execution.
260. The inmate's physical and mental suffering is not explicitly included in the Execution Protocol's considerations for whether to halt further peripheral IV access attempts.
261. DRC Defendants' execution policy, including the Execution Protocol, fails to recognize that each inmate may present unique physical or psychological characteristics that may affect how a particular execution must be carried out while remaining within the bounds of the law.
262. DRC Defendants' execution rehearsals are not modified or tailored to address specific physical or psychological characteristics of any particular condemned inmate.
263. DRC Defendants have failed to prepare, train, or adjust the drug dosages to account for the unique issues any individual condemned inmate may present.
264. DRC Defendants' execution policy, including the Execution Protocol, fails to require a physician to personally supervise or monitor the preparation, administration or disposal of the lethal drug(s).

265. DRC Defendants' execution policy, including the Execution Protocol, fails to require a physician to personally insert a subclavian central line through which the lethal drug(s) may be injected.
266. DRC Defendants' execution policy, including the Execution Protocol, fails to require a physician or any other advanced-practitioner to be on hand to provide necessary medical care during the course of an execution attempt.
267. Other states require the use of physicians during the execution process.
268. A recent change in Ohio law protects an Ohio-licensed physician from any professional discipline that might arise from ethical violations from participating in an execution.
269. DRC Defendants, during the previous failed attempt to execute Romell Broom, used a physician to participate in their unsuccessful efforts.
270. DRC Defendants' execution policy, including the Execution Protocol, fails to contain any provision by which Defendants are able to ensure that they do not violate constitutional prohibitions on executing an incompetent individual in violation of *Ford v. Wainwright*, 477 U.S. 399 (1986), and *Panetti v. Quarterman*, 551 U.S. 930 (2007).
271. DRC Defendants' execution policy, including the Execution Protocol, fails to contain any provision by which Defendants are able to ensure that they do not violate constitutional prohibitions established in *Atkins v. Virginia*, 536 U.S. 304 (2002), and reconfirmed in *Brumfield*

v. Cain, 135 S. Ct. 2269, 192 L. Ed. 2d 356 (2015), on executing an inmate that is categorically ineligible for the death penalty due to his or her intellectual disability.

272. The 2016 Execution Protocol is notable for what it lacks:

- any analytical testing of execution drugs other than a provision stating that any compounded execution drugs will be tested solely for identity and potency, notwithstanding that analytical testing for matters such as sterility, purity, the presence of pyrogens and others are required by USP <797> and, therefore, now required under Ohio law and, accordingly, now required by Defendants' Execution Protocol;
- any requirements or any point of reference for what constitutes a "sample from the batch" of execution drugs to be tested; whether such testing is even remotely relevant to the execution drugs to be used depends in part on the sample size and the batch size—for instance, will one vial in ten be tested? One vial in 1000?;
- any provision expressly limiting the source of any API to be compounded into drugs for an execution to an FDA-registered facility, or expressly prohibiting the use of any API obtained on the grey or black markets;
- any provision to expressly ensure the API supply chain will be subject to inspection and mandatory documentation at each step in the supply chain to help assure that the raw API is not imported, is sterile, is unadulterated, is not contaminated with bacteria or fungus or any other substance, does not contain dangerous allergens or substances that may cause immediate anaphylactic reactions, or is otherwise anything other than pure, raw API for the execution drug in question;
- any provision expressly mandating pre-compounding analytical testing of the raw API to ensure the API is not imported, is sterile, is unadulterated, is not contaminated with bacteria or fungus or any other substance, does not contain dangerous allergens or substances that may cause immediate anaphylactic reactions, or is otherwise anything other than pure, raw API for the execution drug in question;

- any provision expressly for testing the pH level of compounded drugs;
- any provision expressly for testing compounded drugs for purity and sterility, such as for the presence of pyrogens or other bacteria or fungus, allergens or substances that may cause immediate anaphylactic reaction, or other contaminants; testing for identity and potency will not properly identify whether additional substances are contained in the compounded drug;
- any provision to expressly preclude using compounded drugs that are incorrect concentration, or in any way misbranded or adulterated in any way other than identity or potency;
- any provision expressly regarding the requisite minimum qualifications of any compounding pharmacy and any compounding pharmacist to be used, or any provision expressly setting out characteristics that would automatically disqualify a compounding pharmacy or a compounding pharmacist from performing any tasks related to execution drugs;
- any provision expressly regarding the requisite minimum qualifications for any analytical testing entity to be used, or any provision expressly setting out characteristics that would automatically disqualify a testing entity from performing any tasks related to execution drugs;
- any provision expressly requiring that any analytical testing of compounded execution drugs will be done as a separate oversight step by an outside, independent laboratory; that is, there is nothing to expressly preclude DRC from accepting any analytical testing performed by entities that are not truly independent from DRC, the Ohio Attorney General's Office or the local county prosecutor—such as the compounding pharmacy or pharmacist itself or Ohio's BCI crime lab—and which would, therefore, have a vested interest in a particular outcome of the analytical testing that undermines the credibility and reliability of any such testing;
- any provision expressly establishing the required testing protocols to be followed by any testing facility in conducting any analytical testing of execution drugs, or any provision expressly requiring the testing facility in question to even have any written testing protocols for execution drugs at all;

- any provision expressly requiring creation of any documentation of analytical testing allegedly completed, or any provision expressly requiring production of such documentation to any person or entity, let alone an independent expert, for independent verification of the validity of the testing protocol or the testing results;
- any provision expressly making matters related to analytical testing of compounded execution drugs a mandatory, “core” part of the Execution Protocols, thereby rendering it subject to deviation or variation on the whim of the Director or the Director’s designee, whomever that happens to be at a given moment, if proceeding with an execution in strict compliance with the skeletal testing provisions in the protocol would be “difficult, impractical or impossible”;
- any provision expressly requiring the compounder to adhere to current Good Manufacturing Practices (“cGMPs”) for manufacturing the particular drug in question, or any provision expressly requiring the compounder to verify that it is properly set up to compound high-risk sterile injectables;
- any provision expressly requiring mandatory inspection of the compounding pharmacy or outsourcing facility and the entity’s operations;
- any provision expressly requiring that the compounding pharmacy, outsourcing facility, or compounding pharmacist be licensed by the Ohio State Board of Pharmacy or, indeed, by any state’s pharmacy licensing entity;
- any provision expressly requiring adherence to the Beyond-Use Date limits for compounded drugs established under Ohio law;
- any provision expressly recognizing that compliance with the United States Pharmacopeia chapter <797> is required by Ohio Admin. Code § 4729-16-03 for any compounded drugs used in executions;
- any provision expressly recognizing that compliance with section 503A of the Federal Food, Drug, and Cosmetic Act is required by Ohio Admin. Code § 4729-16-03 for any compounded drugs used in executions;

- any provision expressly establishing how compounded execution drugs will be transported, stored or otherwise maintained as required by the relevant state of the compounded drugs (frozen, refrigerated, or room temperature), or any provision expressly mandating that compounded drugs be transported, stored or otherwise maintained as necessary depending on the relevant state of the compounded drugs;
- any provision expressly setting out how the Drug Administrators will prepare compounded execution drugs that are stored in a frozen or refrigerated state, such as when or how frozen compounded execution drugs will be thawed, which is significant because improper procedures such as premature thawing or thawing using inappropriate methods substantially increase the risk of harm from using compounded execution drugs;
- any provision expressly mandating any kind of analytical testing or any other form of verification of identity, identity, adulteration, contamination, pH level, sterility, and other similar concerns related to any execution drug that is imported, whether in bulk form as raw API or in manufactured form;
- any provision expressly recognizing DRC Defendants are explicitly prohibited from using any imported execution drug that was exported by a non-FDA-registered facility, or any provision expressly recognizing DRC Defendants are explicitly prohibited from using any imported execution drug that comes from a grey or black market course, or any provision expressly recognizing DRC Defendants are prohibited from using any drug that is an “unapproved drug” under federal law;
- any provision expressly recognizing Defendants are prohibited from using execution drugs that are obtained, imported, purchased, prescribed, possessed, dispensed, distributed, or administered (and any other terms of art under the federal CSA, federal FDCA or Ohio law) in violation of federal and state laws;
- any provision to expressly ensure that the Warden’s declaration of death of the condemned inmate is in accord with the point at which “death” occurs as defined and governed under Ohio law;

- any provision for use of any methods for genuinely assessing the inmate's consciousness level, awareness level, or any provision for use of any instrument—other than the implied use of a stethoscope by the two persons who will listen to the inmate for heart and lung sounds—to help determine whether the inmate is truly dead as that term is defined under Ohio law;
 - any provision for additional injections of the execution drug before a significant period of time—likely at least 5 or more minutes—has passed;
 - any provision for expressly ensuring emergency resuscitative equipment will be on hand in the Death House, or any provision expressly establishing procedures for, or any Execution Team training for, implementing emergency resuscitative measures when cessation of the inmate's circulatory and respiratory system is still reversible after the Warden has called "time of death."
273. The absence of the above-recited necessary safety and other prophylactic measures related to analytical testing renders the analytical testing provision in the Execution Protocol insufficient to reduce the substantial risk of serious harm presented by using imported or compounded execution drugs.
274. The absence of the above-recited necessary safety and other prophylactic measures substantially increases the risk of serious harm to the inmate when DRC Defendants' Execution Protocol is applied to him.
275. DRC Defendants' execution policy, including the Execution Protocol, fails to contain relevant oversight or procedural protection provisions as to the Drug Source Defendants themselves, or sufficient oversight or procedural protection provisions as to the drug(s) the Drug Source

Defendants provide for use in an execution pursuant to the Execution Protocol.

276. The Execution Protocol contains insufficient provisions by which DRC Defendants will ensure compliance with Core Element # 2, that all execution drugs to be used in a particular execution are, in fact, the specific execution drug type, quantity, sterility level, purity, origin, unadulterated, not misbranded, and legally obtained, as required to be used by the Execution Protocol, making it highly likely that Defendants will deviate from Core Element # 2.
277. The Execution Protocol contains insufficient provisions by which DRC Defendants will ensure compliance with all applicable federal and state statutes and administrative regulations, thus making it highly likely that Defendants will deviate from Core Element # 2's requirements by using execution drugs that are not the drugs required to be used by the Execution Protocol because they are not legally manufactured, imported, compounded, distributed, dispensed, or otherwise provided to DRC Defendants.
278. The Execution Protocol, although providing that a sample of compounded execution drugs will be "analytically tested [for identity and potency] before they are used," contains no explicit mandate that any execution drugs procured from the Drug Source Defendants must be tested for purity, contamination, concentration, pH levels, sterility, adulteration, expiration/beyond its use date, improper storage or

handling, or other factor that might affect an inmate's constitutional rights, making it highly likely that Plaintiff's constitutional rights will be violated through Defendants' use of compounded, imported, or otherwise-sourced execution drugs.

279. The Execution Protocol contains no explicit requirement for any inspections, quality-control verifications, licensure or background checks or any other verification of professional credentials, individual or professional character, qualifications, conflicts of interest, or anything else related to the Drug Source Defendants or facilities in which the Drug Source Defendants will manufacture, process, compound, package, ship, import, store or hold or offer for sale execution drug(s), and as a result of a lack of oversight, serious complications are foreseeable and substantially likely.

1. Plan 1 of Defendants' Execution Protocol – A One-Drug Method Using Pentobarbital

280. Plan 1 of DRC Defendants' Execution Protocol requires the peripheral intravenous injection, via two syringes of 2.5 grams each of pentobarbital, for a total of 5 grams of pentobarbital. In practice, DRC Defendants fill the IV tubing with saline solution before injecting the execution drug, and they flush the IV lines only by virtue of a low-pressure saline drip.

281. Five additional grams of pentobarbital are required to be obtained and kept available in the Equipment Room, to be drawn into two syringes

and administered via peripheral IV injection if the primary five-gram dose of pentobarbital “proves to be insufficient for the procedure.”

282. There is no provision in the Execution Protocol or DRC Defendants’ informal execution policies for ensuring that additional quantities of pentobarbital are kept available in the Equipment Room to be used in an execution, and, upon information and belief, additional quantities of pentobarbital beyond 10 grams will not be present or available for DRC Defendants to use in an execution using Plan 1.
283. DRC Defendants contemplate using pentobarbital obtained under whatever name it may be available from Drug Source Defendants, and from whatever source they can.
284. Use of pentobarbital in an execution carries a substantial risk of creating a paradoxical reaction, which occurs when a drug does not work as intended.
285. A paradoxical reaction to pentobarbital would cause an individual to remain hyper-aware as the execution proceeds. As a result of that heightened state of awareness, such an individual would experience severe pain and needless suffering as the injected lethal drug does its work.

286. The risk of a paradoxical effect is even greater when the individual to whom the drug is being injected has suffered a brain injury or history of head trauma, or has a history of aggression or impulsivity, a history of substance abuse, a history of psychiatric disorders, or characteristics that suggest PTSD.
287. Eyewitness and media accounts of executions in other jurisdictions using pentobarbital suggest that condemned inmates have experienced substantial pain, suffering and an extended duration of execution.
288. Upon information and belief, injection of five grams of pentobarbital via peripheral IV will not cause the condemned inmate to lose awareness and consciousness for a period of minutes following the commencement of the injection.
289. Upon information and belief, injection of five grams of pentobarbital via peripheral IV will cause a condemned inmate to experience substantial pain while still aware or conscious.
290. DRC Defendants' own medical expert at the time, Dr. Mark Dershwitz, has presented testimony in this litigation admitting that pentobarbital can sometimes cause pain even when properly injected.
291. Using pentobarbital to kill in a lethal-injection execution makes it sure or very likely the inmate will suffer a painful heart attack.
292. DRC Defendants know or should know that Plan 1 causes death by suffocation, unless death occurs by a painful heart attack.

293. Two injections of 2.5 grams of the pentobarbital will not act directly to stop Plaintiff's heart.
294. Two injections of 2.5 grams of the pentobarbital will suppress Plaintiff's breathing, creating a lack of oxygen to his heart.
295. The lack of oxygen caused by two injections of 2.5 grams of the pentobarbital will suppress the beating of Plaintiff's heart.
296. After two injections of 2.5 grams of pentobarbital have been completed, Plan 1 of the Execution Protocol calls for an Unnamed and Anonymous Execution Team Member ("Drug Administrator") to reenter the Execution Chamber to inspect the IV site for evidence of incontinence or infiltration and to listen to the prisoner for breathing and heart sounds.
297. If the Drug Administrator does not hear any breathing or heart sounds, an "appropriate medical professional" (the County Coroner) shall evaluate the prisoner to confirm death.
298. Though Plan 1 of DRC Defendants' Execution Protocol does not define the phrase "evaluate the prisoner to confirm death," upon information and belief, by practice, the County Coroner listens to the prisoner for breathing and heart sounds.
299. Though Plan 1 of the Execution Protocol does not define the phrase "evaluate the prisoner to confirm death," upon information and belief, by practice, the County Coroner does not perform ECG or EEG examinations.

300. Though Plan 1 of the Execution Protocol does not define the phrase "sufficient time for death to have occurred," by practice, the Drug Administrator's evaluation and the County Coroner's evaluation both occur within approximately ten minutes following the two injections of 2.5 grams of pentobarbital.
301. Within approximately ten minutes after two injections of 2.5 grams of pentobarbital, Plaintiff's heart and breathing sounds will be undetectable.
302. Under Plan 1 of the Execution Protocol, after the County Coroner confirms death, Defendant Warden will declare Plaintiff dead by announcing a time of death.
303. At the time Defendant Warden will declare Plaintiff dead by announcing a time of death, it is sure or very likely that Plaintiff will still have rhythmic electrical cardiac activity that can be detected through an ECG examination.
304. At the time Defendant Warden will declare Plaintiff dead by announcing a time of death, it is sure or very likely that Plaintiff will still have electrical activity in his brain that can be detected through an EEG examination.
305. Where the activity described in the preceding two paragraphs is present, Plaintiff is clinically and legally alive.

306. It is sure or very likely that Plaintiff's electrical cardiac activity and electrical brain activity will continue for as long as 45 minutes after breathing and heart sounds are undetected under Plan 1.
307. It is sure or very likely that Plaintiff will not have sustained either irreversible cessation of circulatory and respiratory functions or irreversible cessation of all functions of the brain, including the brain stem, at the time Defendants declare him dead and take subsequent actions under the Execution Protocol.
308. The 2016 Execution Protocol contains additional requirements relevant to Plan 1, allegations of which are incorporated here by reference.

2. Plan 2 of DRC Defendants' Execution Protocol – A One-Drug Method Using Sodium Thiopental

309. Plan 2 of DRC Defendants' Execution Protocol requires the peripheral intravenous injection, via five syringes, of five grams of thiopental sodium. In practice, DRC Defendants fill the IV tubing with saline solution before injecting the execution drug, and they flush the IV lines only by virtue of a low-pressure saline drip.
310. Five additional grams of thiopental sodium are required to be obtained and kept available in the Equipment Room, to be drawn into five separate syringes and administered via peripheral IV injection if the primary five-gram dose of thiopental sodium "proves to be insufficient for the procedure."

311. Beyond the 10 grams prepared as described above, nothing in the Execution Protocol or DRC Defendants' informal execution policies ensures that additional quantities of thiopental sodium are kept available in the Equipment Room to be used in an execution. Upon information and belief, additional quantities of thiopental sodium beyond these 10 grams will not be present or available for DRC Defendants to use in an execution using Plan 2.
312. Defendants contemplate using thiopental sodium obtained under whatever name it may be available from Drug Source Defendants, and from whatever source they can.
313. Use of thiopental sodium in an execution carries a substantial risk of creating a paradoxical reaction, which occurs when a drug does not work as intended.
314. A paradoxical reaction to thiopental sodium would cause an individual to remain hyper-aware as the execution proceeds. As a result of that heightened state of awareness, such an individual would experience severe pain and needless suffering from a heart attack or other pain associated with the process as the injected lethal drug does its work.
315. The risk of a paradoxical effect is even greater when the individual to whom the drug is being injected has suffered a brain injury or head trauma, or has a history of aggression or impulsivity, a history of

substance abuse, a history of psychiatric disorders, or characteristics that suggest PTSD.

316. Defendants know or should know that Plan 2 causes death by suffocation, unless death occurs as a result of a painful heart attack.
317. Using thiopental sodium to kill in a lethal-injection execution makes it sure or very likely the inmate will suffer a painful heart attack.
318. Five injections of 1.0 grams of the thiopental sodium will not act directly to stop Plaintiff's heart.
319. Instead, five injections of 1.0 grams of the thiopental sodium will suppress Plaintiff's breathing, creating a lack of oxygen to his heart.
320. The lack of oxygen caused by five injections of 1.0 grams of the thiopental sodium will suppress the beating of Plaintiff's heart.
321. After five injections of 1.0 grams of thiopental sodium have been completed, Plan 2 of DRC Defendants' Execution Protocol calls for an Unnamed and Anonymous Execution Team Member ("Drug Administrator") to reenter the Execution Chamber to inspect the IV site for evidence of incontinence or infiltration and to listen to the prisoner for breathing and heart sounds.
322. If the Drug Administrator does not hear any breathing or heart sounds, an "appropriate medical professional" (the County Coroner) shall evaluate the prisoner to confirm death.
323. Though Plan 2 of DRC Defendants' Execution Protocol does not define the phrase "evaluate the prisoner to confirm death," upon information

and belief, by practice, the County Coroner listens to the prisoner for breathing and heart sounds.

324. Though Plan 2 of the Execution Protocol does not define the phrase "evaluate the prisoner to confirm death," upon information and belief, by practice, the County Coroner does not perform ECG or EEG examinations.
325. Though Plan 2 of the Execution Protocol does not define the phrase "sufficient time for death to have occurred," by practice, the Drug Administrator's evaluation and the County Coroner's evaluation both occur within approximately ten minutes following the five injections of 1.0 grams of thiopental sodium.
326. Within approximately ten minutes after five injections of 1.0 grams of thiopental sodium, Plaintiff's heart and breathing sounds will be undetectable.
327. Under Plan 2 of the Execution Protocol, after the County Coroner confirms death, Defendant Warden will declare Plaintiff dead by announcing a time of death.
328. At the time Defendant Warden will declare Plaintiff dead by announcing a time of death, it is sure or very likely that Plaintiff will still have rhythmic electrical cardiac activity that can be detected through an ECG examination.
329. At the time Defendant Warden will declare Plaintiff dead by announcing a time of death, it is sure or very likely that Plaintiff will

still have electrical activity in his brain that can be detected through an EEG examination.

330. Where the activity described in the preceding two paragraphs is present, Plaintiff is clinically and legally alive.
331. It is sure or very likely that Plaintiff's electrical cardiac activity and electrical brain activity will continue for as long as 45 minutes after breathing and heart sounds are undetected under Plan 2.
332. It is sure or very likely that Plaintiff will not have sustained either irreversible cessation of circulatory and respiratory functions or irreversible cessation of all functions of the brain, including the brain stem, at the time Defendants declare him dead and take subsequent actions under the Execution Protocol.
333. The Execution Protocol contains additional requirements relevant to Plan 2, allegations of which are incorporated here by reference.

3. Plan 3 of DRC Defendants' Execution Protocol – A Three-Drug Method Using Midazolam, A Paralytic, and Potassium Chloride

334. Absent a first drug that will sufficiently render Plaintiff unconscious, unaware, and insensate to severe pain, and that will maintain that state, IV administration of the paralytic drug and potassium chloride and the death caused by one or both of those drugs will be agonizingly painful and torturous to Plaintiff, both physically and psychologically.

335. Confusion has resulted from imprecise use of the term “anesthesia.” The term-of-art of “General Anesthesia” refers to ““the stage of anesthesia that is deep enough to do surgery, for example, where you have loss of awareness, you have loss of consciousness, and no response to noxious stimulus.”” (ECF No. 948 at 32157 (quoting Hr’g Tr., ECF No. 923, PageID 30767–68).)
336. While lay people, courts, and even professionals often imprecisely refer to “anesthesia” as a variety of levels of depressed consciousness, or sedation, the proper delineation between these levels and terms is recognized by the American Society of Anesthesiology (“ASA”). (Stevens Report, ECF No. 836-1, PageID 24810.)
337. “[A]lthough there are different levels of sedation—minimal, moderate, and deep—there is only one level of general anesthesia, which is beyond the deepest level of sedation.” (Decision & Order, ECF No. 948, PageID 32157.)
338. This Court has previously recognized that critical distinction. (See ECF No. 948, PageID 32227 (“[I]n terms of their respective effects on the human body, deep sedation and general anesthesia are distinct.”); *see also id.* at PageID 32157–58, 61–63 (recounting testimony from Dr. Stevens); PageID 32169–72, 74, 78 (describing testimony from Dr. Bergese).)
339. Critically, “because the ‘responsiveness’ associated with general anesthesia is ‘unarousable even with painful stimulus,’ that is the

state in which you would want a condemned inmate to be” considering the undisputed painful effects of the second and third drugs in Ohio’s protocol. (ECF No. 948 (quoting ECF No. 923, PageID 30768).)

340. Plan 3 of DRC Defendants’ Execution Protocol requires the peripheral intravenous injection, via two syringes, of 500 milligrams of midazolam hydrochloride. Those syringes are labeled Syringes 1 and 2.
341. An additional 500 milligrams of midazolam must be kept available in the Equipment Room. If that additional 500 milligrams is withdrawn into syringes for contingency use, those contingency syringes are labeled Syringes A and B.
342. The Sixth Circuit recently concluded that “the protocol’s second and third drugs—the paralytic and potassium chloride, which stops the inmate’s heart—would cause severe pain to a person who is fully conscious.” *In re: Ohio Execution Protocol*, 860 F.3d at 886; (*see also* ECF No. 948, PageID 32226–27 (finding that “administration of a paralytic drug and potassium chloride will cause a person severe pain,” and that such pain is not “limited to persons with particular physical characteristics”).
343. Considerable testimony was presented at a recent evidentiary hearing on the Motion for Preliminary Injunction for Plaintiffs Phillips, Otte, and Tibbetts that demonstrated that the administration of the second

and third drugs would cause agonizing physical and psychological pain to the prisoner being executed. (*See, e.g.*, Hr'g Tr., ECF No. 923, PageID 30777–78 (testimony of Dr. Craig Stevens) (discussing studies in which patients reported feelings of horror, pain, suffocation, and of being buried alive after being paralyzed with a paralytic agent while still conscious); *id.* at PageID 30841 (testimony of Dr. Sergio Bergese) (“it is very terrifying when you talk to people who went through those experiences, absolutely terrifying not being able to move, not being able to – and be fully conscious is quite terrifying [based] on their description”); *see also* Decision & Order, ECF No. 948, PageID 32159–60 (recounting testimony of Dr. Stevens regarding the immense burning pain and suffering caused by potassium chloride); *id.* at PageID 32172 (same, with regard to testimony of Dr. Bergese); *id.* at PageID 32189–90 (same, with regard to testimony of Dr. Joseph Antognini).)

344. Because the paralytic drug does not serve any therapeutic purpose, it is critical that the first drug is properly administered and that it effectuates its claimed purpose to render Plaintiff unconscious, unaware, and insensate to severe pain.
345. If Plaintiff is not properly rendered unconscious, unaware, and insensate to severe pain by the first drug, and that level of unconsciousness, unawareness and insensation is not maintained throughout the execution process, the paralytic will compound the

pain and suffering Plaintiff will experience during his execution by inducing a total paralysis of all his bodily movements and, consequently, his ability to effectively communicate his internal distress. *See Baze v. Rees*, 553 U.S. 35, 73 (2008) (Stevens, J., concurring in the judgment) (“Whatever minimal interest there may be in ensuring that a condemned inmate dies a dignified death, and that witnesses to the execution are not made uncomfortable by an incorrect belief (which could easily be corrected) that the inmate is in pain, is vastly outweighed by the risk that the inmate is actually experiencing excruciating pain that no one can detect.”).

346. Though still aware, conscious, and sensate to severe pain, Plaintiff will be trapped in his own body as the execution moves forward. The pain from the paralytic drug is excruciating; Plaintiff will experience a death akin to being buried alive. That pain and suffering is nothing less than “inhuman and barbarous” torture. *In re: Kemmler*, 136 U.S. 436, 447 (1890). The en banc Sixth Circuit agreed that these drugs cause agonizing pain. *In re: Ohio Execution Protocol*, 860 F.3d at 885–86.
347. The third drug, potassium chloride, is an extremely caustic substance that will activate pain receptors in an inmate’s venous system, and cause excruciating pain as the drug passes through the inmate’s veins.

348. If Plaintiff is not properly rendered unconscious, unaware, and insensate to severe pain by the first drug, yet is paralyzed by the second drug, then the third drug, potassium chloride, will burn as it courses through his veins, until it reaches his heart, ultimately stopping it by inducing cardiac arrest.
349. The Sixth has held that potassium chloride “would cause severe pain” if the inmate is not successfully rendered and maintained unconscious, unaware, and insensate. *Id.* at 886.
350. This searing pain is the chemical equivalent of being burned at the stake, and the heart attack Plaintiff will experience will likewise cause torturous pain and agony. *See Glossip*, 135 S. Ct. at 2781 (Sotomayor, J., dissenting) (“As a result, it leaves petitioners exposed to what may well be the chemical equivalent of being burned at the stake.”).
351. At an undefined point after injection of both syringes of midazolam, a Drug Administrator must reenter the death chamber “to assess the prisoner’s consciousness.”
352. No other assessment of the inmate’s awareness and ability to experience and feel noxious stimuli will be conducted.
353. There are no procedures or provisions made to assess the inmate’s awareness level and ability to experience and feel pain that would allow Defendants to make those determinations accurately.

354. Indeed, the specifics of the “consciousness check” mentioned in the Execution Protocol are undefined.
355. Several states require a waiting period of some number of minutes after injection of the first drug in a three-drug lethal injection protocol before the paralytic drug can be injected.
356. In those “delayed injection states,” there is significant evidence that inmates remain conscious, aware, or at least sensate to severe pain after the midazolam has reached its peak/maximum effective level.
357. Defendants, like a few states, are “rapid injection states,” such that they inject the paralytic drug very quickly after they have nominally finished injection of the first drug.
358. In those “rapid injection states,” evidence of awareness, consciousness, and sensation to severe pain is often covered up by the chemical curtain of the paralytic agent.
359. All evidence indicates that Defendants will only check for responsive actions.
360. While responsive action by the prisoner would indicate awareness, lack of responsive action is not evidence of lack of awareness.
361. For instance, lack of responsive action may indicate only that Plaintiff may be sedated deeply enough that he is unable to manifest any responsive actions, even though he remains aware and/or sensate to feel and experience the effects of the execution drugs.

362. The absence of responsive action would also not demonstrate the level of sedation is beyond that which is able to be overcome by noxious stimuli such as pain caused by the bodily effects of midazolam, or the feelings of suffocation and psychological torment caused by the paralytic drug, or the intense burning sensations and painful heart attack caused by injection of a lethal dose of potassium chloride.
363. During the execution of Ronald Phillips, a Drug Administrator entered the death chamber to perform the “consciousness check” approximately forty-five seconds after Syringe 2 was completed.
364. During the execution of Gary Otte, a Drug Administrator entered the death chamber to perform the “consciousness check” approximately one minute or less after Syringe 2 was completed.
365. Upon information and belief, Defendants intend to enter the death chamber to perform the “consciousness check” less than one minute after Syringe 2 is completed during Plaintiff’s execution.
366. The methods by which DRC Defendants perform the “consciousness check” include saying the inmate’s name out loud, touching the white of the eye, touching the eyelashes, or pinching the inmate’s finger nailbed.
367. These techniques are used by paramedics and EMTs to determine whether a person needs emergency resuscitative care to establish and maintain an operating airway in emergency trauma situations.

368. These techniques are not able to accurately determine whether a condemned inmate is fully unconscious, insensate to severe pain, and unaware at the level akin to General Anesthesia.
369. Upon information and belief, DRC Defendants know that what they perform are, in fact “reflex checks,” which are not capable of assessing whether the person is at a level of unconsciousness, unawareness, and insensation akin to that associated with General Anesthesia.
370. Upon information and belief, DRC Defendants believe a person who appears to “be asleep” or who does not respond to a verbal prompt or their reflex checks is “unconscious.”
371. Upon information and belief, DRC Defendants believe that appearing superficially to be “unconscious” means the person is fully unconscious, fully unaware and unable to feel or experience noxious stimuli including severe pain, at a level akin to that associated with General Anesthesia.
372. The Execution Protocol fails to provide for how the “consciousness check” should or shall be done, or at what time following administration of the first two syringes the Drug Administrator shall enter the death chamber to perform that assessment.
373. Evidence of a prisoner talking or clenching and unclenching his hands is evidence of higher-level brain functions that would be associated with consciousness. (*See Hr’g Tr., ECF No. 923, PageID 30849–53.*)

374. Midazolam does not cause the depression in circulation and drop in blood pressure that sodium thiopental does.
375. A blood pressure cuff would be able to reveal an increase in blood pressure in Plaintiff after he is injected with 500 mg. or more of midazolam and the other phenomena that follow in Defendants' execution protocol.
376. That increase in blood pressure is essentially equivalent to the showing of the perception of pain, thus demonstrating that Plaintiff remains sensate to the severe pain caused by Defendants' execution protocol.
377. An EKG machine would reveal data about Plaintiff's cardiovascular/circulatory system operation that would demonstrate Plaintiff remains sensate to pain after injection of 500 mg. or more of midazolam.
378. An EEG machine (including a BIS machine) would reveal data about Plaintiff's brain functions that would demonstrate Plaintiff remains conscious, aware, and/or sensate to pain after injection of 500 mg. or more of midazolam.
379. Defendants do not use any monitoring technology in their "consciousness check."
380. Thus, the Execution Protocol fails to provide for any genuine assessment of the inmate's level of consciousness, his awareness level or ability to experience and feel severe pain or other noxious stimuli.

381. It is sure or very likely that Plaintiff will be aware, conscious, or sensate to severe pain when he obstructs following injection of the midazolam, or when he is injected with the paralytic drug, or when he is injected with the potassium chloride.
382. Defendants inject the paralytic agent very quickly after injection of midazolam, to paralyze the inmate and thus hide any outward signs that the inmate remains conscious, aware, or sensate to severe pain and suffering.
383. Defendants injected the paralytic agent in the Ronald Phillips execution one minute and thirty-nine seconds after they concluded injection of the midazolam.
384. Defendants injected the paralytic agent in the Gary Otte execution one minute and ten seconds after they concluded injection of the midazolam.
385. Upon information and belief, Defendants will inject the paralytic agent in Plaintiff's execution in approximately the same ultra-short time period as used in the Phillips and Otte executions.
386. If the inmate is found to be "unconscious," then DRC Defendants will commence with administration of the second and third drugs.
387. No Drug Administrator performs any inspection of the IV site(s) for evidence of incontinence or infiltration until after the third drug has been administered.

388. If the inmate is found to be “conscious” after injection of the first drug, then the Drug Administrator, the second Drug Administrator, the Warden, the Director and any Auxiliary Team Member will consult. The IV sites may be checked and changed at that time. The Warden will then decide how to proceed, and may simply wait for the passage of time, or request an additional undefined assessment by a Drug Administrator, or direct administration of Syringes A and B.
389. If contingency Syringes A and B are injected, then the Execution Protocol contemplates repeating the previously explained steps again.
390. Beyond the 500 or 1000 milligrams prepared as described above, nothing in the Execution Protocol or DRC Defendants’ informal execution policies ensures that additional quantities of midazolam are kept available in the Equipment Room to be used in an execution. Upon information and belief, additional quantities of midazolam beyond these 1000 milligrams will not be present or available in the Equipment Room for DRC Defendants to use in an execution using Plan 3.
391. After injection of midazolam and purported confirmation that the inmate is “unconscious,” a Drug Administrator will inject, via two syringes labeled Syringes 3 and 4, a paralytic drug.
392. Syringes 3 and 4 may contain 100 milligrams of vecuronium bromide; or 100 milligrams of pancuronium bromide; or 1000 milligrams of rocuronium bromide.

393. After injection of the paralytic drug, a Drug Administrator will inject, via two syringes labeled Syringes 5 and 6, 240 milliequivalents of potassium chloride.
394. In practice, DRC Defendants fill the IV tubing with saline solution before injecting the first execution drug in Plan 3, and they flush the IV lines only by virtue of a low-pressure saline drip during and following completion of the injections of each of the three types of drugs. They do not employ a high-pressure saline flush following any of the syringes which would ensure that the entire dose was completely injected into the inmate.
395. Due to the lack of a true saline flush, it is substantially likely that some amount of one or more of the three drugs in Plan 3 does not reach the inmate during the course of the execution.
396. Defendants contemplate using any of the drugs in Plan 3 obtained under whatever name each drug may be available from Drug Source Defendants, and from whatever source they can.
397. Use of midazolam in an execution carries a substantial risk of creating a paradoxical reaction, which occurs when a drug does not work as intended.
398. A paradoxical reaction to midazolam would cause an individual to remain hyper-aware as the execution proceeds. As a result of that heightened state of awareness, such an individual would experience severe pain and needless suffering from injection of the paralytic drug

- and potassium chloride, suffocation, or a heart attack or other pain associated with the process as the injected lethal drug does its work.
399. The risk of a paradoxical effect is even greater when the individual to whom the drug is being injected has suffered a brain injury or head trauma, or has a history of aggression or impulsivity, a history of substance abuse, a history of psychiatric disorders, or characteristics that suggest PTSD.
400. Defendants know or should know that Plan 3 causes death by suffocation or as a result of a painful heart attack.
401. Using midazolam to kill in a lethal-injection execution makes it sure or very likely the inmate will be conscious, aware and able to feel and experience the horror and severe pain of suffering a painful heart attack or suffocating to death, or the severe pain and suffering associated with dying from the injection of those drugs in a lethal injection.
402. Using the paralytic drug to kill in a lethal injection execution creates an absolute certainty, beyond just sure or very likely, of unconstitutional pain and suffering if the inmate is not rendered unconscious, unaware and insensate, unable to feel and experience noxious stimuli such as the severe pain associated with injection of the paralytic agent or the process of dying from the effects of that drug.

403. Using the potassium chloride to kill in a lethal injection execution creates an absolute certainty, beyond just sure or very likely, of unconstitutional pain and suffering if the inmate is not rendered unconscious, unaware and insensate, unable to feel and experience noxious stimuli such as the severe pain associated with injection of potassium chloride or the process of dying from the effects of that drug.
404. After injection of 500 mg. of midazolam has been completed, Plan 3 of DRC Defendants' Execution Protocol calls for an Unnamed and Anonymous Execution Team Member ("Drug Administrator") to reenter the Execution Chamber to "assess the prisoner's consciousness." No other assessment of the inmate's genuine level of consciousness, awareness and ability to experience and feel noxious stimuli such as severe pain will be conducted, and there are no procedures or provisions made to assess the inmate's consciousness level, awareness level and ability to experience and feel severe pain that might allow Defendants to even possibly make those determinations accurately.
405. The specifics of the "consciousness check" mentioned in the Execution Protocol are undefined. But in any event, the "consciousness check" is insufficient to determine whether the condemned inmate has been, in fact, rendered and maintained

unconscious, unaware and unable to feel and experience severe pain at the level associated with General Anesthesia.

406. Responsive action by the inmate would indicate consciousness or awareness or sensation to severe pain, but advances in brain science establish that lack of responsive action is not evidence of lack of consciousness or awareness, nor would lack of responsive action demonstrate the state akin to that associated with General Anesthesia, the level of anesthesia beyond that which is able to be overcome by noxious stimuli such as severe pain caused by the bodily effects of midazolam, or the feelings of suffocation and burning caused by the paralytic drug, or the intense burning sensations and painful heart attack caused by injection of a lethal dose of potassium chloride.
407. Once the paralytic drug is delivered, none of DRC Defendants are capable of making, and are not competent to make, any meaningful assessment of the paralyzed inmate without the assistance of mechanical aids such as EEG-based monitors, blood pressure monitors, EKG monitors, and the other types of assessment methods mentioned throughout this Fourth Amended Omnibus Complaint. Indeed, the Execution Protocol does not even require any “consciousness check” after the paralytic is administered.
408. Injection of 500 mg. of midazolam will not act directly to stop Plaintiff's heart.

409. Instead, 500 mg. of midazolam will suppress Plaintiff's breathing, creating a lack of oxygen to his heart.
410. The lack of oxygen caused by 500 mg. of midazolam will suppress the beating of Plaintiff's heart.
411. Injection of the paralytic drug will paralyze Plaintiff's musculature, causing him to suffocate because the muscles required to breathe cannot function.
412. Injection of the potassium chloride will cause Plaintiff to suffer a massive heart attack.
413. After injection of all three drugs in Plan 3 has been completed, the Execution Protocol calls for a Drug Administrator to reenter the Execution Chamber "to inspect the IV site for evidence of incontinence or infiltration and to listen to the prisoner for breathing and heart sounds."
414. If the Drug Administrator does not hear any breathing or heart sounds, an "appropriate medical professional" (the County Coroner) shall evaluate the prisoner to confirm death.
415. Though Plan 3 of DRC Defendants' Execution Protocol does not define the phrase "evaluate the prisoner to confirm death," upon information and belief, by practice, the County Coroner listens to the prisoner for breathing and heart sounds.
416. Though Plan 3 of the Execution Protocol does not define the phrase "evaluate the prisoner to confirm death," upon information and belief,

- by practice, the County Coroner does not perform ECG or EEG examinations, nor is a blood pressure cuff used.
417. Though Plan 3 of the Execution Protocol does not define the phrase “sufficient time for death to have occurred,” by practice, the Drug Administrator’s evaluation and the County Coroner’s evaluation both occur within approximately ten minutes following initiation of the injection of the execution drugs.
418. Within approximately ten or more minutes after injection of the three drugs in Plan 3, Plaintiff’s heart and breathing sounds will be undetectable.
419. Under Plan 3 of the Execution Protocol, after the County Coroner confirms death, Defendant Warden will declare Plaintiff dead by announcing a time of death.
420. At the time Defendant Warden will declare Plaintiff dead by announcing a time of death, there is a substantial risk that Plaintiff will still have cardiac activity that can be detected through an ECG examination.
421. At the time Defendant Warden will declare Plaintiff dead by announcing a time of death, there is a substantial risk that Plaintiff will still have electrical activity in his brain that can be detected through an EEG examination.
422. Where the activity described in the preceding two paragraphs is present, Plaintiff is clinically and legally alive.

423. It is sure or very likely that Plaintiff's electrical cardiac activity and electrical brain activity will continue for as long as 30 minutes or more after breathing and heart sounds are undetected under Plan 3.
424. It is sure or very likely that Plaintiff will not have sustained either irreversible cessation of circulatory and respiratory functions or irreversible cessation of all functions of the brain, including the brain stem, at the time Defendants declare him dead and take subsequent actions under the Execution Protocol.
425. The Execution Protocol contains additional requirements relevant to Plan 3, allegations of which are incorporated here by reference.

D. Additional allegations related to midazolam.

426. Midazolam is a Schedule IV depressant under the Controlled Substances Act. See 21 C.F.R. § 1308.14.
427. Midazolam (also sold under the trade name Hypnovel™ and Versed™) is a short-acting, water-soluble benzodiazepine used most commonly as a premedication (*i.e.*, in advance of anesthesia) for sedation.
428. The FDA-approved intravenous dose for an adult patient is 1 milligram to 2.5 milligrams to induce sedation.
429. Labeling instructions caution that high doses (*e.g.*, more than 1 milligram) must be titrated (the “push rate”) slowly in order to be effective.
430. Specifically, the FDA-approved label counsels that doses of 1-to-2 milligrams be administered over the course of three minutes.

431. To be effective, midazolam must be stored at temperatures between 68 and 77 degrees Fahrenheit. It typically has a shelf life of three years from manufacture.
432. As an ever-growing body of evidence from executions using midazolam demonstrates, midazolam, whether alone or in combination with hydromorphone or any other drugs, is unsuitable for use in human executions, as DRC Defendants know or should know or recklessly disregard.
433. Midazolam is particularly unsuitable as the first drug in a three-drug method that includes the paralytic drug and potassium chloride. Midazolam is much less suitable for that purpose than sodium thiopental or pentobarbital. It is sure or very likely—indeed, a virtual certainty—that midazolam will fail to render Plaintiff sufficiently unconscious, or unaware, or insensate as required to protect against Plaintiff experiencing the severe pain and suffering associated with injection of the second and third drugs and the process of dying from those drugs.
434. Unless Plaintiff is rendered unconscious, unaware, and insensate to severe pain, such as the state equivalent to General Anesthesia and when a BIS monitor would read 60 or below, it is sure or very likely that he will experience the severe pain and suffering caused by injection of the second and third drugs, the operation of those drugs, and the process of dying from those drugs.

435. If Plaintiff is merely rendered “hypnotic” (*i.e.*, superficially “asleep,” not opening his eyes on command, not responding to an eyelash reflex check), that is insufficient to protect him against experiencing the severe pain and suffering associated with lethal injection execution involving the second and third drugs.
436. It is sure or very likely that the maximum effect of midazolam as measured on an EEG machine/BIS monitor is insufficient to render Plaintiff sufficiently unconscious, unaware, and insensate to the severe pain and suffering associated with lethal injection execution involving the second and third drugs.
437. It is sure or very likely that midazolam at any dose is incapable of inducing Plaintiff to a state of unconsciousness, unawareness and insensation equivalent to that associated with General Anesthesia.
438. It is sure or very likely that it will take approximately 5 to 12 minutes or more from the completion of injection for midazolam injected intravenously to reach maximal effect as measured on an EEG machine/BIS monitor.
439. It is also sure or very likely that the maximum effect of midazolam will not be sustained without a continuous infusion of additional amounts of midazolam through a secondary, dedicated IV line.
440. Midazolam has an initial rapid onset, within the first thirty seconds of injection and perhaps as much as two to three minutes after injection.

441. It is sure or very likely that Plaintiff will show the outwards signs of initial onset of midazolam within two to three minutes.
442. But that initial onset and the level of sedation associated with it is not the same as the maximum sedative effect of midazolam as measured by the suppression of brain waives using EEG measurements.
443. The rudimentary “consciousness checks” that Defendants perform are, in actuality, reflex checks.
444. Reflex checks are incapable of assessing whether Plaintiff is truly unconscious, unaware, and insensate to the severe pain and suffering associated with the second and third drugs and the process of dying from those drugs.
445. It is sure or very likely that even if Plaintiff appears non-responsive to the reflex checks Defendants call “consciousness checks,” he will still be sufficiently conscious, aware and/or sensate to severe pain to experience the severe pain and suffering that follows with the second and third drugs.
446. As the midazolam begins to take effect, the condemned inmate may appear to be sedated and superficially appear to be “unconscious” to the unsophisticated observer.
447. The accounts of executions using midazolam, including the Phillips and Otte executions, are consistent in this regard. Regardless of the dose, the inmate very quickly appears to be sedated or even “unconscious.”

448. However, studies based on EEG measurements demonstrate that even though the inmate appears to be completely sedated or even “unconscious,” the midazolam is only beginning to take effect and is far from its peak effectiveness at less than two minutes.
449. Midazolam does not reach its peak effectiveness for sedating an inmate until four to five minutes and as much as twelve minutes, after it is fully injected, regardless of the amount of the injection. Prior to four to five minutes having elapsed after injection of midazolam is completed, at the very least, the inmate cannot be fully sedated, let alone in a state of unconsciousness, unawareness and insensation akin to General Anesthesia.
450. It is extremely likely—a virtual certainty—that midazolam, at any dosage and even at maximum/peak effect sustained for an extended period of time throughout the remainder of the execution process, will not be able to render and maintain Plaintiff sufficiently unconscious, unaware and insensate to the severe pain and suffering associated with the second and third drugs in the execution protocol.
451. It is sure or very likely that midazolam, at any dosage and even at maximum/peak effect sustained for an extended period of time throughout the remainder of the execution process by a continuous infusion, will not be able to render and maintain Plaintiff sufficiently unconscious, unaware, and insensate to the severe pain and suffering

associated with obstruction and air hunger that will follow injection of the midazolam.

452. As demonstrated in the execution of Ronald Phillips, in which Defendants injected the paralytic drug one minute and 39 seconds after they finished injecting the midazolam, and the execution of Gary Otte, in which Defendants injected the paralytic drug one minute and 10 seconds after the finished injecting the midazolam, Defendants will inject the paralytic drug extremely quickly after conclusion of administration of the midazolam.
453. The evidence from the Phillips and Otte executions also demonstrates that DRC Defendants will conduct the “consciousness checks” starting around forty-five seconds after they finished injecting the midazolam.
454. The “consciousness checks” during the Phillips execution took seconds, and certainly a maximum of twenty-eight seconds or less to complete.
455. The “consciousness checks” during the Otte execution took only seconds, and certainly a maximum of twenty-one second or less to complete.
456. That time frame, before the midazolam could have reached maximum effectiveness, makes it sure or very likely that DRC Defendants conduct only reflex checks, not a genuine assessment of the inmate’s

true level of consciousness, awareness and sensation to severe pain and suffereing.

457. Injecting the paralytic so rapidly makes it sure or very likely that Plaintiff will experience the severe pain and horrific suffering caused by the paralytic, even if he appears superficially to be “unconscious.”
458. Injecting the paralytic so rapidly makes it sure or very likely that Defendants will administer the chemical curtain of the paralytic at a time when Plaintiff is not sufficiently unconscious, unaware and insensate to severe pain, but that he will be unable to outwardly show his reaction to the severe pain and suffering he is enduring.
459. Evidence from the recent Phillips execution shows that Defendants injected the potassium chloride starting at five minutes and seventeen seconds after they finished injecting the midazolam.
460. Evidence from the recent Otte execution shows that Defendants injected the potassium chloride starting at five minutes and twenty-eight seconds after they finished injecting the midazolam.
461. That makes it sure or very likely that DRC Defendants will inject Plaintiff with the potassium chloride before the midazolam has reached its peak effect level.
462. Rocuronium bromides takes approximately two minutes to take full effect.

463. Defendants waited two minutes and four seconds between the conclusion of injecting the paralytic and the start of injecting the potassium chloride during the Phillips execution.
464. Defendants waited two minutes and eleven seconds between the conclusion of injecting the paralytic and the start of injecting the potassium chloride during the Otte execution.
465. By waiting for at least two minutes from the conclusion of injection of the paralytic before they began injecting the potassium chloride, Defendants tried to ensure that the paralytic would be fully operative such that the inmate was completely paralyzed at the start of the injection of the potassium chloride.
466. It is thus sure or very likely that inmates Otte and Phillips experienced the severe pain and suffering associated with the potassium chloride, but that they were unable to outwardly show that they were suffering that severe pain, appearing on the surface, instead, to be “unconscious.”
467. It is also sure or very likely that Plaintiff will experience the severe pain and suffering associated with the potassium chloride, but that he will be unable to outwardly show that he is suffering that severe pain, appearing on the surface, instead, to be “unconscious.”
468. Unlike pentobarbital and sodium thiopental, midazolam is not a barbiturate. It is a benzodiazepine, which can induce sedation and amnesia, but it cannot protect against sensations of pain: it has no

- pain-relieving properties and cannot produce the level of unconsciousness, unawareness and insensation to severe pain necessary to not experience the severe pain and suffering that will result from the second and third drugs in Ohio's three-drug execution protocol—*i.e.*, the lack of consciousness, awareness and sensation associated with the state of General Anesthesia in a medical context.
469. One can still consciously experience one's surroundings and feel severe pain and horrific stimuli such as that associated with the second and third drugs in Ohio's protocol while under sedation using midazolam.
470. Based on known scientific information regarding its mechanism of action, midazolam is unable to ensure that Plaintiff will be, and will remain, in a state such that he is unconscious, unaware, and insensate to severe pain and suffering.
471. The amnestic effect of midazolam is irrelevant in an execution context; that only prevents the subject from remembering what he experienced, but does not prevent the subject from being aware of the experience as it is happening. (*See* Decl. David Waisel, M.D., ECF No. 381, PageID 11590.)
472. Midazolam is not an analgesic—that is, it has no pain-relieving properties—and is not typically used as an anesthetic agent. *Id.*

473. Injection of midazolam does not prevent awareness or feeling severely painful stimuli such as the pain and suffering associated with the second and third execution drugs.
474. Injection of midazolam does not render and maintain a person unconscious, unaware and insensate at the level associated with General Anesthesia. A person subjected to lethal injection using midazolam will be substantially likely to suffer severe physical pain and torturous mental suffering and anguish, and will be substantially likely to be aware of that pain and suffering.
475. One of the characteristics of midazolam is that it cannot relieve pain. A person who is not rendered and maintained unconscious at the level akin to that of General Anesthesia, or is otherwise rendered superficially unconscious or unaware by midazolam, and then subjected to severe pain will return to awareness and experience that pain. For that reason, midazolam is not suitable as a stand-alone anesthetic to render and maintain unconsciousness, unawareness, and insensation at the level akin to that of General Anesthesia.
476. The FDA has not approved midazolam for use as a stand-alone anesthetic to render and maintain General Anesthesia, and it is not used as such.
477. Due to the way in which midazolam operates in the brain, it begins to lose effectiveness very rapidly if no continuous infusion is used to

maintain its maximum level of sedation, much more quickly than barbiturates such as pentobarbital and sodium thiopental.

478. As recent executions in other states involving midazolam confirm, it is sure or very likely that the midazolam will either not reach maximum effect fast enough or wear off sufficiently for Plaintiff to be conscious or aware or sensate at some level before the paralytic drug and potassium chloride have been completely administered to Plaintiff. And that means it is sure or very likely that Plaintiff will be aware of feeling the indisputably excruciating pain cause by each of the second and third drugs.
479. Further, midazolam is subject to a phenomenon known as a “ceiling effect,” which limits the effect of large doses. It is not, at any dose, able to reliably keep a person unconscious, unaware and insensate during the administration of severely painful stimuli, nor can it render and maintain a level of unconsciousness, unawareness and insensation akin to General Anesthesia.
480. Benzodiazepines like midazolam have no effect on the central nervous system (the brain and spinal cord) in amounts above their ceiling effect, because the receptors on which midazolam acts become saturated. Upon information and belief, midazolam’s ceiling effect level is in or about the range of 25 to 200 mg, which is substantially lower than the 500 or 1000 mg. injected under the Execution Protocol.

481. Thus, administration of any midazolam above 25 to 200 mg. to Plaintiff will have no significance to whether Plaintiff will be conscious or aware or sensate to severe pain and experience the effects of midazolam itself, the effects of the paralytic, and the effects of potassium chloride.
482. At or about a dose of 25 or even 200 mg. midazolam injected rapidly at the start of the final stage of the Execution Protocol, it is still sure or very likely that Plaintiff will be or become aware and sensate to severe pain when exposed to the noxious stimuli he will experience from air hunger, a painful heart attack, suffocation and the terror of being paralyzed from the paralytic drug or the sensation of being burned alive from the inside from potassium chloride.
483. The high dose of midazolam required by the Execution Protocol is misleading for another reason: a significant portion—more than 50% and perhaps as much as 75%—of a large injected dose of midazolam, injected very rapidly into the bloodstream under the terms of the Execution Protocol, will precipitate, *i.e.*, fall out of the solution, at the site of injection as it is first diluted with blood. This means that a reduced portion of the original 500 mg. dose of midazolam—and substantially likely to be less than the ceiling effect level of 25 to 200 mg.—is available to exert action in the brain and render Plaintiff unconscious, unaware and insensate to severe pain.

484. The extent of precipitation of midazolam depends on the conditions of administration. Administration in accordance with the manufacturer's package insert so as to reduce or eliminate the chances of precipitation upon injection requires an injection/push rate of "at least 2 minutes" for a clinical dose, which equates to approximately 2 mg/minute. Injecting 500 mg. as required under the Execution Protocol, at a rate needed to avoid precipitating the midazolam at the injection site, would require 250 minutes (over four hours), not including the additional time to switch between the two syringes.
485. A faster push rate virtually guarantees a substantial amount of the injected midazolam will precipitate upon injection.
486. A faster push rate also significantly increases the likelihood that a patent IV portal will fail ("blowing a vein") and thus significantly increases the risk of not administering the full dose of midazolam in the first place.
487. Upon information and belief, DRC Defendants will inject Plaintiff with midazolam at a push rate significantly faster than 2 mg/minute. Upon information and belief, DRC Defendants will inject Plaintiff with the full 500 mg. of midazolam in approximately 2-3 minutes (including the time required to switch between the two syringes), a push rate of approximately 166 mg./minute to 250 mg./minute, which is approximately 100 times faster than the 2 mg./minute push

- rate necessary to ensure against IV problems and precipitation upon injection.
488. Defendants' use of midazolam in their execution protocol makes it sure or very likely that Plaintiff will suffer air hunger and/or suffocation.
489. Air hunger is the inability to satisfy the physiologic and psychologic urge to breath, similar to suffocation. It is the inability to take a breath to satisfy the body's involuntary drive to breathe. Air hunger and/or suffocation is a terrifying, horrifying, and painful experience.
In re Ohio Execution Protocol Litig., 994 F. Supp. 2d at 912.
490. An intravenous injection of midazolam will not prevent Plaintiff from being conscious, or feeling and/or being aware of the severe pain, horrific sensation and agony of air hunger and/or suffocation, or the effects of dying from IV injection of the three drugs in Ohio's three-drug execution protocol.
491. A large dose of midazolam, such as the 500 mg (or 1000 mg, if the contingency syringes are used) provided in the 2016 Execution Protocol, also carries a substantial risk of producing tonic-clonic seizures (generalized seizures that affect the entire brain) and convulsions. Such conditions result in severe pain and suffering.
492. Use of midazolam (like with pentobarbital or thiopental sodium) also makes it very likely that a paradoxical reaction will occur.

493. A paradoxical reaction to the lethal drug(s) would cause an individual to remain hyper-aware as the execution proceeds. As a result of that heightened state of awareness, such an individual will be sure or very likely to experience severe pain and needless suffering as the injected lethal drug(s) do their work.
494. It is sure or very likely that a paradoxical reaction will occur when midazolam is administered in high doses to individuals like Plaintiff with a history of brain damage or head trauma, aggression or impulsivity, a history of alcohol or substance abuse, or other psychiatric disorders.
495. Due to the rapid injection of the paralytic agent, however, it is sure or very likely that Plaintiff will be unable to convey the fact that he is experiencing a paradoxical reaction and the severe pain and horrific suffering associated with Defendants' execution protocol.
496. Injection of midazolam as directed by DRC Defendants' Execution Protocol will also make it sure or very likely that Plaintiff will be conscious, aware, or at least sensate to experience the excruciating pain of a heart attack.
497. The objective risk of substantial harm to an inmate when using midazolam as part of a lethal-injection execution method was too great for Kentucky. Kentucky, which had "modeled its execution process on Ohio's," created regulations to use a combination of midazolam and hydromorphone in its executions, but Kentucky's

Attorney General informed a Kentucky court that the Commonwealth would be eliminating the two-drug protocol from its regulations before ever using it, “cit[ing] ‘recent events in other states.’” Associated Press, *Kentucky drops 2-drug executions, reworking method*, Daily Mail, Nov. 14, 2014.³ According to the spokeswoman for the Commonwealth, “Kentucky will not take any risks with its protocols for lethal injection; therefore, we are going to eliminate this methodology [of lethal injection] from our regulations.” *Id.*

498. Arizona, the state that executed Joseph Wood using a lethal injection method that included injection of approximately 750 mg. of midazolam, recently informed a federal district court that it will be changing its execution protocol to remove midazolam from the protocol, and that the state will never again use midazolam as part of its execution protocol. *See Wood v. Ryan*, No. 2:14-cv-1447, ECF No. 145, p. 2 (D. Ariz. Oct. 17, 2016) (brief filed by defendants asserting that regardless of any matters related to availability, Arizona “has committed to removing midazolam as an option from [Arizona’s execution protocol] and now unequivocally commits not to use midazolam again, even if it becomes available.”).

³ Available at <http://www.dailymail.co.uk/wires/ap/article-2834665/Kentucky-drops-2-drug-executions-reworking-method.html>.

499. On or about January 4, 2017, the State of Florida revised its lethal injection execution protocol, eliminating midazolam as the first drug in Florida's three-drug execution method. *See* http://www.dc.state.fl.us/oth/deathrow/lethal-injection-procedures-as-of_01-04-17.pdf.
500. Defendants have no scientific basis to include midazolam in the Execution Protocol, whether by itself or as the first of a three-drug execution method.
501. Defendants did not include midazolam in the Execution Protocol on the basis of any alleged belief that using midazolam to carry out a lethal injection execution is more humane, safer, or more effective than any FDA-approved barbiturate.
502. Defendants pioneered the use of midazolam in a lethal injection protocol when they selected it to combine with hydromorphone in a back-up execution protocol to be injected intramuscularly after the failed attempt to execute Romell Broom.
503. Midazolam in that two-drug execution method was selected for its compatibility to mix with hydromorphone in the same syringe and the alleged synergistic effect the two drugs created, which would, in Defendants' view, suppress the circulatory and respiratory system sufficiently to cause death.
504. Now, however, Defendants are using midazolam as the critical first drug in a protocol that includes two other indisputably severely

painful drugs, which makes it essential that the first drug produce unconsciousness, unawareness and insensation to severe pain at the level associated with General Anesthesia.

505.

E. Additional allegations related to pancuronium bromide, vecuronium bromide, and rocuronium bromide.

506. Each of pancuronium bromide, vecuronium bromide and rocuronium bromide is a paralytic agent, causing a complete loss of control over a person's musculature, including but not limited to the diaphragm, the arms, legs, mouth, neck, and muscles in the chest wall. For ease of reference herein, pancuronium bromide, rocuronium bromide, and vecuronium bromide are referred to collectively as "the paralytic drug" or "paralytic agent."
507. By cutting off an inmate's ability to control his diaphragm, any of these paralytic agents prevents ventilation and, accordingly, the ability to breathe.
508. Even when administered effectively, these paralytic agents affect neither consciousness nor awareness nor the perception of pain, nor do they prevent the recipient from suffering a slow and excruciatingly painful death by asphyxiation.
509. Being injected with any of these three paralytic agents while still conscious or aware or able to feel pain will cause an inmate to experience the horrific and torturous feeling of being unable to move the muscles required for respiration and thus slowly suffocating to

death while being unable to communicate that circumstance, similar to the experience of being buried alive.

510. Executing an inmate by way of a paralytic drug without first rendering and keeping that inmate unconscious and unaware and insensate to severe pain will cause that inmate to experience unconstitutional physical pain and mental suffering.
511. Defendants have not included the paralytic drug in the Execution Protocol for the purpose of causing the inmate's death.
512. Defendants have included the paralytic drug in the Execution Protocol for the purpose of masking the visible signs of the potassium chloride acting on the condemned inmate to give the misleading impression that the inmate is fully unconscious and unaware and insensate at all times following the injection of the lethal drugs.
513. Defendants used Rocuronium bromide during the executions of Ronald Phillips on July 26, 2017, and Gary Otte on September 13, 2017.
514. Per product labeling and the manufacturer's insert, rocuronium bromide should be stored in a refrigerator at a specific temperature range.
515. Per product labeling and the manufacturer's insert, rocuronium bromide should not be frozen.

516. Per product labeling and the manufacturer's insert, upon removal from refrigeration to room temperature storage conditions, rocuronium bromide must be used within 60 days.
517. Upon information and belief, Defendants remove twice as many rocuronium vials as necessary for execution from the refrigerated storage to room temperature conditions in the Equipment Room. Defendants then return unused vials of rocuronium bromide to the refrigerator several hours later, after the execution is complete.
518. Upon information and belief, Defendants do not mark or segregate the rocuronium bromide vials that were removed from the refrigerated storage to room temperature conditions and then returned to refrigerated conditions in any way.
519. Upon information and belief, Defendants do not store separately the rocuronium bromide vials that were removed to room temperature conditions and then returned to refrigerated conditions.
520. Per regulations of the Ohio State Board of Pharmacy, a drug not stored as indicated in the product label is an adulterated drug. Ohio Admin. Code § 4729-9-01(B)(3).
521. Vials of rocuronium bromide that were removed from the refrigerated storage to room temperature conditions and were not used within 60 days have become adulterated drugs.
522. Upon information and belief, Defendants have no way of distinguishing between the vials of rocuronium bromide that have

become adulterated from the stock of vials of rocuronium bromide that were kept refrigerated the entire time.

523. Upon information and belief, Defendants will use adulterated rocuronium bromide in executing Plaintiff.

F. Additional allegations related to potassium chloride.

524. Potassium chloride is an extremely caustic substance that will activate pain receptors in an inmate's venous system, and cause excruciating pain as the drug passes through the inmate's veins.
525. Being injected with potassium chloride causes burning sensations. Being injected with potassium chloride at the levels provided in the Execution Protocol while the inmate is still conscious or aware or able to feel and experience pain will cause the inmate to experience the physical pain and torturous mental anguish and suffering on the level of being burned alive at the stake.
526. Potassium chloride injected at the levels provided in the Execution Protocol will also cause an excruciatingly painful heart attack.

G. Additional allegations related to using pentobarbital, thiopental sodium or midazolam for an execution.

527. A "New Drug" under the federal Food, Drug & Cosmetic Act (21 U.S.C. § 321(p)) and Ohio Revised Code § 3715.01(9)(a), means a drug that is "not generally recognized . . . as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof."
528. Thiopental sodium, pentobarbital and midazolam are Dangerous Drugs under Ohio law, for which Ohio law requires they may only be

- dispensed upon a prescription, Ohio Rev. Code § 4729.01(F)(1)(b), and for which Ohio law requires compliance with federal FDCA labeling and new drug approval requirements under 21 U.S.C. § 301, et seq. See Ohio Rev. Code §§ 3719.01(D), 3719(BB), 4729.01(F)(1)(a).
529. The FDA must approve any New Drug before the drug is introduced into interstate commerce, 21 U.S.C. § 355(a), and before any drug is sold, delivered for sale, held for sale, or given away, Ohio Rev. Code § 3715.65.
530. FDA approval of a New Drug must be for specific uses of a drug. To obtain FDA approval, drug manufacturers are required to demonstrate, through clinical trials, the safety and efficacy of a New Drug for each intended use or indication.
531. Any pentobarbital, thiopental sodium, midazolam, paralytic drug or potassium chloride DRC Defendants might use for a lethal-injection execution of Plaintiff would have been introduced into interstate commerce, or sold, delivered for sale, held for sale, or given away.
532. Thiopental sodium has never been approved by FDA for any intended use, and is thus considered an unapproved New Drug such that all Defendants may not, regardless of the source, lawfully introduce thiopental sodium into interstate commerce, or sell, deliver for sale, hold for sale, or give away thiopental sodium.

533. No drug is, or ever has been, approved by the FDA as safe and effective for the purpose of causing a “quick and painless” death required by Ohio’s execution statute.
534. Therefore, when used for the purpose of causing death in a human execution, Defendants’ actions involving any of the execution drugs in Defendants’ Execution Protocol constitute using unapproved New Drugs under the FDCA and Ohio state law. *See* 21 U.S.C. §§ 321(p), 355; Ohio Rev. Code § 3715.65(A).
535. Before a New Drug can lawfully be administered to humans (other than through the doctor-patient relationship in the practice of medicine), an “investigational new drug application (‘IND’)” must be submitted by the entity administering the drug. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 697–98 (D.C. Cir. 2007).
536. To obtain approval of an IND Application, the applicant must engage in clinical investigation. Thus, to administer any of the drugs in the Execution Protocol to inmates to cause their execution, DRC Defendants are required to submit an IND Application to the FDA and “shall not begin a clinical investigation . . . until the investigation is subject to an IND which is in effect.” 21 C.F.R. § 312.20(a)–(b).
537. DRC Defendants flout these federal and state laws. DRC Defendants have never submitted any IND Application to the FDA for using any of the drugs in the Execution Protocol. Nor have DRC Defendants ever

taken steps to submit an IND Application for using pentobarbital, thiopental sodium, midazolam, the paralytic drug, or potassium chloride in an execution, and neither Ohio’s execution statute nor the Execution Protocol includes such a requirement.

538. DRC Defendants have not submitted and do not intend to submit an IND Application for any of the drugs Defendants plan to use under the Execution Protocol to attempt Plaintiff’s lethal-injection execution.
539. Ohio’s lethal-injection statute and the Execution Protocol, as written and as implemented, therefore purport to authorize DRC Defendants’ use of unapproved New Drugs on a human in Plaintiff’s attempted execution without satisfying the IND Application requirement established under the applicable federal and state regulations and statutes.
540. Federal and state laws prohibit introduction into commerce of any adulterated or misbranded product: “The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded” is a “Prohibited Act.” 21 U.S.C. § 331; Ohio Rev. Code § 3715.52(A)(1).
541. Under federal law, a product is misbranded if it is “health-endangering when used [as] . . . prescribed.” 21 U.S.C. § 352(j).
542. Under Ohio state law, a product is misbranded if it “is dangerous to health when used [as] . . . prescribed.” Ohio Rev. Code § 3715.64.

543. Drug Source Defendants engage in a Prohibited Act under both state and Federal law by manufacturing, selling, delivering, holding or offering for sale any of the drugs in the Execution Protocol to DRC Defendants to be used for a lethal-injection execution—and thus Drug Source Defendants are violating federal and state law by engaging in such actions—because those drugs are, by definition, misbranded by virtue of being “health-endangering” and “dangerous to health” because they will be used to execute Plaintiff.
544. Under federal law, a drug is adulterated if “the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.” 21 U.S.C. § 351(a)(2)(B).
545. A drug is also adulterated under federal law if “it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium.” 21 U.S.C. § 351(b).

546. Under Ohio state law, a drug is adulterated if it “purports to be or is represented as a drug the name of which is recognized in the United States pharmacopoeia and national formulary, or any supplement to them, and its strength differs from or its quality or purity falls below the standard set forth in those compendiums.” Ohio Rev. Code § 3715.63(A)(5).
547. The DRC Defendants previously recognized the importance of not using adulterated controlled substances for execution drugs, when they agreed they would not use adulterated thiopental sodium for executions. *See ¶¶ 884–885 below.*
548. Drug Source Defendants engage in a Prohibited Act under federal law by manufacturing, selling, delivering, holding or offering for sale a drug product, namely any of the drugs in the Execution Protocol for DRC Defendants to use in a lethal-injection execution of Plaintiff, and those drugs are not manufactured, processed, packed or held in a facility that is in conformity with current good manufacturing practices, and thus Drug Source Defendants are violating federal and state law by engaging in such actions.

549. Drug Source Defendants engage in a Prohibited Act under both federal and Ohio state law by manufacturing, selling, delivering, holding for sale or offering for sale a drug product, namely any of the drugs in the Execution Protocol for DRC Defendants to use in a lethal-injection execution of Plaintiff, that is not the same strength, quality and purity as that drug as identified in the USP and national formulary, and thus Drug Source Defendants are violating federal and state law by engaging in such actions.
550. The standard of practice of pharmacy in Ohio requires “(5) Performing drug regimen reviews with individuals by discussing all of the drugs that the individual is taking and explaining the interactions of the drugs; (6) Performing drug utilization reviews with licensed health professionals authorized to prescribe drugs when the pharmacist determines that an individual with a prescription has a drug regimen that warrants additional discussion with the prescriber.” Ohio Rev. Code § 4729.01(B).
551. Prospective Drug Utilization Reviews are intended to maximize potential therapeutic benefit while minimizing potential harm to the patient through a review of the patient’s drug therapy regimen including the current prescription in question.
552. The pharmacist is directed to ultimately use “professional judgment whether and in the patient’s best interest to dispense the prescription.” Ohio Admin. Code § 4729-5-20.

553. A pharmacist is required under Ohio law to perform the Prospective Drug Utilization Review. Ohio Admin. Code § 4729-5-21(B)(2) (“A pharmacist when dispensing a prescription must . . . perform prospective drug utilization review pursuant to rule 4729-5-20 of the Administrative Code”).
554. Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 violate these responsibilities under Ohio law to the patient’s best interests when the drug product they dispense is for the purpose of killing Plaintiff, and thus Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 violate state law by engaging in such actions.
555. Ohio law also requires Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 to act “in a manner that is in the best interest of the patients served and to comply with all state and federal laws.” Ohio Admin. Code § 4729-9-02(A)(2), (B).
556. Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 violate these state regulations by compounding, dispensing, distributing, or any other similar action the drugs for DRC Defendants to use to carry out a lethal-injection execution, because acting to facilitate the death of Plaintiff is not in his best interests, and because Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 violate several state and federal laws in the course of their actions related to execution drugs.

557. Controlled substances may not be dispensed without a valid prescription from a medical practitioner. 21 U.S.C. § 829(a)–(b).
558. Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100, like all pharmacists and pharmacies, may only dispense a prescription drug product on the receipt of a valid drug order (Prescription) from a licensed practitioner authorized to prescribe.
559. The Ohio Medical Practice Act (Ohio Admin. Code § 4731-11-02), states that physicians cannot utilize a controlled substance for other than “legitimate therapeutic purposes,” (§ 4731-11-02(F)), which would preclude their writing a prescription for execution drugs.
560. The restrictions under Ohio law on what may constitute a “valid” prescription are so critical they are reiterated in two separate provisions of Ohio’s Administrative Code: the regulation governing “Manner of processing a prescription” (Ohio Admin. Code § 4729-5-21), and the regulation governing “Manner of issuance of a prescription” (Ohio Admin. Code § 4729-5-30).
561. Ohio law governing the “manner of processing a prescription” requires that a “prescription, **to be valid, must be** issued for a **legitimate medical purpose** by an individual **prescriber** acting in the **usual course** of his/her **professional practice.**” Ohio Admin. Code § 4729-5-21(A) (emphases added).

562. The “responsibility for the proper prescribing is upon the prescriber, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. **An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription** and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law.” *Id.* (emphasis added).
563. Ohio law governing the “manner of issuance of a prescription” similarly requires that a “prescription, **to be valid, must be** issued for a **legitimate medical purpose** by an individual **prescriber** acting in the **usual course** of his/her **professional practice.**” Ohio Admin. Code § 4729-5-30 (emphases added).
564. An “order purporting to be a prescription issued not in the usual course of **bona fide treatment of a patient is not a prescription** and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law.” *Id.* (emphases added)
565. Ohio law also requires that a prescription must “[b]e issued in compliance with all applicable federal and state laws, rules, and regulations.” Ohio Admin. Code § 4729-5-30(18).

566. Accordingly, these Ohio prescription requirements echo those of requirements set forth under the federal Controlled Substances Act's explanation of the "purpose of issue of prescription": "A prescription for a controlled substance to be effective **must** be issued for a **legitimate medical purpose** by an individual **practitioner** acting in the **usual course** of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. **An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829)** and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." 21 C.F.R. § 1306.04(a) (emphases added).
567. A pharmacist may not lawfully prepare and dispense a prescription drug product, such as controlled substances like pentobarbital or thiopental sodium or midazolam, for anything other than a legitimate medical purpose.

568. The only valid prescription under federal and Ohio state law is one that is issued for a legitimate medical purpose, issued by an individual health-care practitioner with the requisite license to prescribe drugs, in the usual course of professional treatment or for legitimate or authorized research.
569. None of those DRC Defendants involved in procuring execution drugs or the Chief Justice of the Ohio Supreme Court is, under the law, an individual practitioner acting in the usual course who might be authorized to prescribe prescription drugs.
570. Execution is not a legitimate medical purpose.
571. Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 are therefore violating federal and state law by preparing and dispensing a prescription drug product, namely any of the drugs in the Execution Protocol for DRC Defendants, to be used to carry out a lethal-injection execution of unspecified condemned inmates.
572. General dispensing of controlled substances is also prohibited, because a valid prescription must be patient-specific. *See* 21 C.F.R. § 1306.04(b) (“A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.”).

573. DRC Defendants rely solely on a resolution issued by the Ohio State Board of Pharmacy, R-2012-051, to claim that a certified copy of a Death Warrant issued by the Ohio Supreme Court, ordering the execution of an inmate by lethal injection, has the same force and effect as a proper order for administration of the drug(s).
574. The State of Ohio delegated to the Ohio State Board of Pharmacy authority to “adopt rules in accordance with Chapter 119 of the Revised Code, not inconsistent with the law, as may be necessary to carry out the purposes of and to enforce the provisions of this chapter.” Ohio Admin Code § 4729.26. In turn, Chapter 119 of the Administrative Code sets out the requirements to follow the necessary administrative procedures. Resolution R-2012-051 was not a validly enacted rule under that chapter, and is therefore invalid as a matter of Ohio state law.
575. Additionally, Resolution R-2012-051 is invalid as a matter of law because it is “inconsistent with the law” to the extent that it purports to authorize Defendants to obtain, provide, compound, administer, dispense, or distribute controlled substances without a prescription that satisfies the minimum requirements for a valid prescription under federal statutes and regulations or state statute.

576. The minimum requirements for what constitutes a valid prescription for prescription drugs established under federal law may not be overruled or disregarded by any provision in Ohio state law, regardless of whether any state statute or regulation was validly enacted under state law.
577. DRC Defendants do not obtain new execution drugs for each individual execution; instead DRC Defendants obtain a supply whenever they can, to be used for future executions.
578. This practice conflicts with the prohibition on “general dispensing” of controlled substances and thus DRC Defendants violate federal and state law by engaging in such actions.
579. Drug Source Defendants do not produce, provide, distribute or dispense execution drugs for each execution specific to the particular condemned inmate, but rather produce, provide, distribute or dispense a large supply that is not individualized to a particular condemned inmate. This practice conflicts with the prohibition on “general dispensing” of controlled substances and thus Drug Source Defendants violate federal and state law by engaging in such actions.
580. Defendants are violating federal and state law by preparing and dispensing the drugs in the Execution Protocol other than to a single, identified individual when the execution drugs are prepared and dispensed for DRC Defendants to use to carry out one or more lethal-injection executions.

581. The only FDA-approved form of pentobarbital is manufactured, sold and distributed as Nembutal.
582. At all times relevant hereto until December of 2011, the only FDA-approved source of Nembutal was the pharmaceutical company Lundbeck (“Lundbeck”).
583. In July of 2011, Lundbeck instituted distribution controls to prevent the legitimate sale of Nembutal to departments of corrections in states that use lethal injection for capital punishment.
584. In December, 2011, Lundbeck sold its interests in Nembutal to Akorn Pharmaceuticals (“Akorn”).
585. The only current FDA-approved source of Nembutal is Akorn. Akorn has retained Lundbeck’s distribution controls.
586. All stocks of Nembutal sold prior to the institution of the Lundbeck/Akorn controls have expired.
587. Upon information and belief, Akorn has requested that supplies of the company’s products that could be used for lethal injection be returned.
588. Defendants therefore have no legitimate or legal source of Nembutal.
589. Nembutal is available for purchase on the commercial market, however, regardless of whether it is available to DRC Defendants for executions.

590. At least one other State has continued to be able to purchase Nembutal for use in executions even after Lundbeck/Akorn's distribution controls.⁴
591. Any pentobarbital to be used in executing Plaintiff will come from Drug Source Defendants via either: (a) the illegal importation of pentobarbital, a Schedule II controlled substance; or, (b) the illegal compounding of pentobarbital.
592. Federal and Ohio state drug control laws strictly govern possession, transportation, transfer, use, dispensing, and other such aspects related to controlled substances which are listed on "schedules" under federal statutes and regulations.
593. The Controlled Substances Act creates a comprehensive, closed regulatory regime criminalizing the unauthorized manufacture, distribution, dispensing, and possession of substances.
594. Pentobarbital is a Schedule II-N controlled substance under the federal Controlled Substances Act, its implementing regulations and analogous or related federal and/or state laws such as the federal Food, Drug and Cosmetic Act. 21 C.F.R. § 1308.12.

⁴ See Chris McDaniel, *Missouri Execution Drug Purchases Revealed*, BuzzFeed News, Jan. 8, 2017, available at https://www.buzzfeed.com/chrismdaniel/missouri-execution-drug-purchases-revealed?utm_term=.maW8zrOX9#.dxJbBV4Pn.

595. By virtue of that fact, pentobarbital is a Controlled Substance under Ohio law. *See* Ohio Rev. Code §§ 3719.01(C), 3719.41, 3719.43 and 3719.44.
596. Thiopental sodium is a Schedule III controlled substance under the federal Controlled Substances Act, its implementing regulations and analogous or related federal laws such as the federal Food, Drug and Cosmetic Act. *See* 21 U.S.C. §§ 801–814; 21 C.F.R. § 1308.13(c)(3).
597. By virtue of that fact, sodium thiopental is a Controlled Substance under Ohio law. *See* Ohio Rev. Code §§ 3719.01(C), 3719.41, 3719.43 and 3719.44.
598. Midazolam is a Schedule IV controlled substance under the relevant statutes and implementing regulations and analogous or related federal laws.
599. By virtue of that fact, midazolam is a Controlled Substance under Ohio law. *See* Ohio Rev. Code §§ 3719.01(C), 3719.41, 3719.43 and 3719.44.
600. Upon information and belief, the only manufacturers of FDA-approved midazolam have instituted strict end-user controls analogous to Akorn's restrictions on Nembutol.
601. Defendants therefore have no legitimate or legal source of FDA-approved midazolam.

602. Midazolam by its brand name is available for purchase on the commercial market, however, regardless of whether it is available to DRC Defendants for executions.
603. Any midazaolam to be used in executing Plaintiff will come from Drug Source Defendants via: (a) the illegal importation of midazolam, a Schedule IV controlled substance; (b) the illegal compounding of midazolam; or (c) subterfuge and deception to fraudulently induce a source of the drug to make it available to Defendants for use in executions.
604. The Controlled Substances Act allows prescription of drugs only if they have a currently accepted medical use. 21 U.S.C. § 812(b).
605. The Controlled Substances Act also requires a “medical purpose” for dispensing the least controlled substances of those on the schedules. § 829(c).
606. The Controlled Substances Act, in its reporting provision, defines a “valid prescription” as one “issued for a legitimate medical purpose.” § 830(b)(3)(A)(ii).
607. Under the Controlled Substances Act, physicians are considered to be acting as practitioners under the statute if they dispense controlled substances “in the course of professional practice.” § 802(21).
608. The enforcement provision of the Controlled Substances Act states that “[e]xcept as authorized . . . it shall be unlawful for any person

- knowingly or intentionally . . . to . . . distribute or dispense . . . a controlled substance.” 21 U.S.C. § 841(a).
609. Schedule II substances are generally available only pursuant to a written, nonrefillable prescription by a physician. *See* 21 U.S.C. § 829(a).
610. The Supreme Court of the United States has held that, under the Controlled Substances Act, dispensing controlled substances without a valid prescription is a federal crime. *See Gonzales v. Oregon*, 546 U.S. 243, 250–57 (2006).
611. Although it is generally a crime to dispense controlled substances, an exemption is made for duly licensed and registered physicians and other entities that may lawfully prescribe controlled substances. 21 U.S.C. § 829.
612. The Attorney General of the United States has passed a regulation pursuant to the Controlled Substances Act requiring that every prescription for a controlled substance be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. *See* 21 CFR § 1306.04(a).
613. Defendants, or others acting on Defendants’ behalf, do not obtain or dispense the lethal execution drugs pursuant to a valid prescription.
614. Upon information and belief, no duly licensed and registered physician or other entity prescribes the controlled substances DRC Defendants use to carry out a lethal-injection execution.

H. Allegations related to compounded execution drugs.

615. Using compounded execution drugs creates a sure or very likely risk of serious harm to Plaintiff, as identified in other paragraphs of this Fourth Amended Omnibus Complaint.
616. Modern day pharmacy practice relies almost entirely on pharmaceutical manufacturers to provide finished dosage forms (tablets, capsules, injectables, etc.) for the pharmacist's use.
617. American healthcare providers and patients have long relied on the regulation of pharmaceutical manufacturers by the FDA in order to set the standard for identity, purity, potency, and efficacy of prescription medications.
618. Manufacturers are heavily regulated to insure the quality of the dosage form and the safety and clinical effectiveness of the product.
619. Extensive (and expensive) testing is required before marketing as well as with each new batch produced, to insure quality, safety and effectiveness.
620. In very limited circumstances when a thoroughly tested commercial product will not fulfill a patient's needs, pharmacists are allowed to bypass the FDA quality requirements imposed on commercial manufacturers to extemporaneously prepare a personalized dosage form for a patient through the process called compounding.

621. Some of the DRC Defendants' previous execution protocols permitted only the use of "trade name" or "generic" drugs for a lethal-injection execution.
622. The DRC Defendants have eliminated those protective measures by including compounded drugs as among the execution drugs permitted under the Execution Protocol.
623. Compounded execution drugs provided to DRC Defendants by any of the Drug Source Defendants will not be manufactured, mixed, assembled, packaged, labeled, distributed, transferred, dispensed, or administered:
- a) pursuant to a prescription issued by a licensed health professional authorized to prescribe drugs, or
 - b) pursuant to a modification of a prescription made in accordance with a consult agreement, or
 - c) as an incident to research, teaching activities or chemical analysis, or
 - d) in anticipation of orders for drugs pursuant to valid prescriptions.
624. Traditional pharmacy compounding is a practice of the profession of pharmacy by which a licensed pharmacist, using Active Pharmaceutical Ingredients (APIs) and inactive ingredients obtained from FDA-approved facilities, combines, mixes, or alters ingredients in response to a prescription to create a medication tailored to the individual medical/therapeutic needs of an individual patient when

- that patient's individual needs cannot be met with an FDA-approved product.
625. On the other hand, non-traditional compounding pharmacy practice involved in the process of making lethal injection drugs resembles drug manufacturing more than it does practice of pharmacy. Non-traditional compounding involves the use of raw ingredients to manufacture a copy or substitute for an FDA-approved drug.
626. Even drugs made according to the enforceable sterile compounding standards issued by the United States Pharmacopeia (USP) Chapter 797 have a low standard of sterility assurance compared to the federal standard for manufactured, FDA-approved drugs.
627. The quality of raw bulk product, or Active Pharmaceutical Ingredients (“APIs”), used in compounding is suspect. Because of high profit margins and low quality controls in the compounding industry, the market for API attracts counterfeiters. These counterfeit bulk drugs pose a health hazard because their manufacturer is often unknown, impurity profile is unknown, and the age, storage, and manufacturing environment likewise remain a mystery.
628. Compounded drugs are not FDA-approved for any purpose. This means that the FDA does not verify the identity, purity, strength, potency, quality, safety, or effectiveness of compounded drugs. *See*

Sarah Sellers & Wulf H. Utian, *Pharmacy Compounding Primer for Physicians: Prescriber Beware*, 72 Drugs 2043, 20444–45 (2012).⁵

629. This also means that compounded drugs lack any FDA finding of safety, efficacy, and manufacturing quality. *Id.* at 2048.
630. Chemicals that have not have been manufactured in a FDA-registered facility under current Good Manufacturing Practices have no assurance of consistent quality from lot to lot or from container to container.
631. DRC Defendants previously recognized the importance of not using compounded controlled substances for execution drugs, when they agreed they would not use compounded thiopental sodium for executions.
632. Defendants involved in producing compounded drugs are subject to federal and state drug laws identified in preceding paragraphs, including those regulating misbranded or adulterated drugs or the prescription requirements.
633. Defendants involved in producing compounded drugs are also subject to regulations, both federal and state, specific to compounding. These federal and Ohio state laws and regulations define two categories of compounding:

⁵ Available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3695671/>.

- (1) drugs compounded in a Pharmacy by a pharmacist, 21 U.S.C. § 353a and Ohio Admin. Code § 4729-16-03 (identified herein as a “503A Compounding Pharmacy”); or
 - (2) sterile drugs compounded in an Outsourcing Facility, 21 U.S.C. § 353b and Ohio Admin. Code 4729-16-02 (identified herein as a “503B Outsourcing Facility”).
634. The New Drug provisions of the FDCA are waived for activities within these two categories. Outside of these two avenues, however, a compounded drug product is an unauthorized New Drug, which may not be introduced or delivered into interstate commerce (21 U.S.C. § 355(a)), or sold, delivered for sale, held for sale, or given away (Ohio Rev. Code § 3715.65).
635. Manufacture, sale, or delivery, holding or offering for sale compounded drugs by Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 to be used by DRC Defendants for an execution is a Prohibited Act under federal and Ohio state law—and thus Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 are violating federal and state law by engaging in such actions—because those compounded drugs would be misbranded and/or adulterated drug products.
636. Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100, regardless of whether acting as a 503A Compounding Pharmacy or a 503B Outsourcing Facility, are violating

the federal and Ohio state law by compounding, dispensing, and distributing any execution drugs that are controlled substances.

637. Pharmacies may only dispense, not manufacture or distribute, controlled substances. 21 U.S.C. § 822(a)(2).
638. Dispensing a controlled substance such as pentobarbital or thiopental sodium or midazolam is prohibited except in certain circumstances.
639. Under 21 U.S.C. § 802(10), “dispensing” a controlled substance “means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term ‘dispenser’ means a practitioner who so delivers a controlled substance to an ultimate user or research subject.”
640. In an execution context, the inmate such as Plaintiff would be the “ultimate user,” which means that, under the law, only Plaintiff himself would be able to legally take delivery of compounded execution drugs from Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100.
641. Because Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 will dispense the compounded controlled substance(s) to be used for an execution to a person or entity other than Plaintiff, Defendants Unknown Pharmacies #1–100

and Defendants Unknown Pharmacists #1–100 are violating federal and state law.

642. When pharmacies such as Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 provide controlled substances to anyone but the ultimate user (*i.e.*, the patient or a member of the patient’s household), those pharmacies are distributing, not dispensing controlled substances.
643. Pharmacies such as Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 are prohibited from distributing any controlled substances under the CSA unless the amount of controlled substances distributed is strictly limited (5% or less of all units dispensed or distributed) and other specific criteria are met. 21 C.F.R. § 1307.11(a). For example, the distribution must be “for the purpose of general dispensing by the practitioner to patients.” 21 C.F.R. § 1307.11.
644. Because Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 are not distributing pentobarbital or thiopental sodium or midazolam to a practitioner for general dispensing to patients, but rather distributing the drug to DRC personnel to be used to kill Plaintiff and other condemned inmates, Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 are violating federal law by their actions.

645. Any distribution of compounded drugs to a prescriber is prohibited by Ohio law unless the drug is used “(a) [t]o treat an emergency situation; (b) [f]or an unanticipated procedure for which a time delay would negatively affect patient outcome; (c)[f]or diagnostic purposes.” Ohio Admin. Code § 4729-9-25(A)(2).
646. Carrying out a lethal-injection execution is not an “emergency situation,” nor is it “unanticipated” nor is the pentobarbital or thiopental sodium or midazolam used in an execution context “for diagnostic purposes.” Thus, none of those exceptions apply in the execution context, and Defendants are also violating this provision of Ohio state law by their actions.
647. If Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 are operating as a 503A Compounding Pharmacy, they cannot compound, prepare, sell, dispense, or deliver drugs for DRC Defendants to use in an execution while remaining in compliance with all federal and state laws related to compounding.
648. If any of Defendants Unknown Pharmacies #1-100 and Defendants Unknown Pharmacists #1-100 are acting as a 503A Compounding Pharmacy, they cannot legally compound or dispense a drug product compounded for an execution because of restrictions on how and when a 503A Compounding Pharmacy may compound and dispense drugs.

649. Similar to requirements for the dispensing of commercially available products, Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 cannot compound or dispense or sell a compounded product—including execution drugs identified in Defendants’ Execution Protocol—unless it is pursuant to “. . . a **valid prescription order** or a notation, approved by the **prescribing practitioner**, on the prescription order that a compounded product is **necessary for the identified patient . . .**” 21 U.S.C. § 353a(a).
650. Ohio law mandates compliance with the federal § 353a. See Ohio Admin. Code § 4729-16-03(C).
651. Ohio law also mandates that a “prescription shall be compounded and dispensed only pursuant to a specific order for an individual patient issued by a prescriber.” Ohio Admin. Code § 4729-16-03(J). See also Ohio State Board of Pharmacy, *Compounding In Ohio*, updated May 20, 2015.⁶
652. There can be no valid prescription for compounded execution drugs, for the reasons explained in previous paragraphs.

⁶ Available at <http://www.pharmacy.ohio.gov/Documents/TDDD/General/Compounding%20in%20Ohio.pdf>.

653. Nor can there be any “notation . . . that a compounded product is necessary for the identified patient” because a drug product intended to kill the identified patient is not “necessary for the identified patient” as required by law.
654. Thus Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100, if acting as a 503A Compounding Pharmacist, will lack a legitimate prescription or notation from the prescribing practitioners of the necessity for a compounded drug, and thus Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 are violating federal and state law by engaging in any preparation or provision of drugs to be used by DRC Defendants for a lethal injection execution.
655. Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 are unable to satisfy the highly stringent requirements established in 21 U.S.C. § 353a(b), incorporated into Ohio law via Ohio Administrative Code § 4729-16-03(C), and thus Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 are violating those provisions of federal and state law by preparing and providing compounded sterile injectable controlled substances for DRC Defendants to use in carrying out an execution.

656. If Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 are operating as a 503B Outsourcing Facility, they cannot compound, prepare, sell, dispense, or deliver drugs for DRC Defendants to use in an execution while remaining in compliance with all federal and state laws related to compounding.
657. Compounding by a 503B Outsourcing Facility is subject to and regulated by the FDA’s Current Good Manufacturing Practices (cGMP), the same set of requirements for quality assurance that are imposed on other commercial pharmaceutical manufacturers.
658. Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 are violating federal and state law by failing to comply with cGMPs, such as the requirement that any manufacturer conduct its own analytical testing and other testing (such as for the presence of pyrogens or other contaminants) throughout the manufacturing process before the drug is released to any other entity.
659. A 503B Outsourcing Facility is prohibited from producing drug products that are “essentially a copy of an approved drug.” 21 U.S.C. § 353b(a)(5).
660. Under the law, a compounded drug is “essentially a copy of an approved drug” if, in relevant part, it is identical or nearly identical to a drug with an approved New Drug Application (NDA) or an Abbreviated New Drug Application (ANDA). 21 U.S.C. § 353b(d)(2).

661. That restriction effectively prohibits a 503B Outsourcing Facility from producing and distributing copies of drugs which are FDA approved which may be used in an Ohio execution, *i.e.*, pentobarbital, midazolam, the paralytic drug, and potassium chloride.
662. At this time, none of pentobarbital, midazolam, or the paralytic drug appears on the FDA's drug shortage list, and thus the provision in federal law that might permit copies of approved drugs in short supply does not apply here for those drugs.
663. Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100, if acting as a 503B Outsourcing Facility, are violating federal and state law by producing any pentobarbital, midazolam, or the paralytic drug (for executions or for any other reason), because the compounded drug product would be identical or nearly identical to an FDA-approved drug that is not on the FDA's drug shortage list at this time.
664. 503B Outsourcing Facilities are also not permitted to compounded products using bulk drug substances that do not appear on a list established by the Secretary of the Department of Health and Human Services identifying bulk drug substances for which there is a clinical need, or the drug compounded from that bulk substance appears on the drug shortage list in effect under section 356e of this title at the time of compounding, distribution, and dispensing. 21 U.S.C. § 353b(a)(2)(A).

665. At this time, pentobarbital, midazolam and the paralytic drug do not appear on the list identifying bulk drug substances for which there is a clinical need, nor does pentobarbital appear on the drug shortage list under 21 U.S.C. § 356e.
666. Thus, Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100, if acting as a 503B Outsourcing Facility, are violating federal and state law by compounding pentobarbital, midazolam, or the paralytic drug because using bulk drug (API) of those drugs is prohibited by this provision of the law.
667. Additionally, bulk drug substance may not be permissibly compounded by a 503B Outsourcing Facility if the bulk drug substance to be compounded is not accompanied by a valid certificate of analysis. 21 U.S.C. § 353b(a)(2)(D).
668. Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 cannot and/or will not produce a valid certificate of analysis for any drugs compounded for DRC Defendants to use in carrying out a lethal-injection execution, and thus Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 are violating these provisions of federal and state law.

669. Unlike FDA-approved drugs manufactured by a reliable manufacturer and intended for therapeutic uses, drugs manufactured, compounded, imported, other otherwise provided by the Drug Source Defendants to DRC Defendants for injection into a condemned inmate such as Plaintiff are intended solely to kill that condemned inmate.
670. The Drug Source Defendants will know or will be able to readily ascertain the identity of the person or persons who are to be killed using the execution drugs they provide to DRC Defendants; they will know they are providing drugs that will be used to kill Plaintiff.
671. The Drug Source Defendants will know or will be able to readily ascertain the nature of the crime for which Plaintiff is to be executed.
672. There is no oversight, testing, checks, auditing or assessment for compliance with the law of the Drug Source Defendants themselves, their manufacturing or compounding facilities, their distribution, storage, packing, or anything else related to Drug Source Defendants' provision of drugs to be injected into a condemned inmate to carry out an execution.

673. Just as important, the Drug Source Defendants *will know* that there is no such oversight, testing, checks, auditing or assessment of their compliance with the law, in general and as related to provision of execution drugs to be used to kill Plaintiff, because they have been assured anonymity and immunity from certain professional repercussions under Ohio state law for a period of years from the point at which their assistance to DRC Defendants ceases.
674. Some Defendants—including at least one Drug Administrator—have admitted that they have thought of the inmate’s victim and that victim’s family while attempting to carry out an execution.
675. Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100, by each agreeing to violate his or her professional oaths, the relevant standards of care and federal and Ohio state law by manufacturing drugs exclusively to kill in a lethal-injection execution, necessarily lack the requisite ethical standards required of licensed pharmacists.
676. Any of the drugs in the Execution Protocol that will be used for injections may be compounded only in a “sterile” compounding facility.

677. Sterile compounding pharmacies located within the State of Ohio are subject to certain federal and state regulations and relevant United States Pharmacopeia guidelines as adopted by the Ohio Board of Pharmacy by rule or policy. *See, e.g.*, Ohio Admin. Code § 4729-19-04.
678. Compounding pharmacies are not regularly or consistently inspected.
679. In fact, the Ohio Pharmacy Board does not track the number of compounding in-state pharmacies in Ohio, nor does Ohio require and/or provide training for inspectors to inspect compounding pharmacies.
680. Ohio does not track the number of inspections of compounding pharmacies in the state within a given year, nor does Ohio track the number of concerns about compounding pharmacies any such inspections reveal.
681. Ohio also does not track the number of disciplinary actions taken against in-state pharmacies for any reason over the last decade, nor does Ohio track the number of concerns with out-of-state compounding pharmacies that have been raised.

682. Errors that occur at compounding pharmacies may be caused by factors including: (a) use of substandard or contaminated APIs; (b) use of an incorrect formula to prepare a prescription drug; (c) maintenance of liquid dosages at inappropriately high temperatures, which may lead to chemical changes in the liquid; (d) failure to maintain a sterile facility and/or procedures; (e) failure to maintain manufacturing equipment in a sterile manner; (f) failure to properly store compounded products; (g) mislabeling medication; and (h) labeling medication with improper dispensing instructions for patient use.
683. When errors occur in compounding sterile preparations, harm can result from microbial contamination, excessive bacterial endotoxins, variability in intended strength and pH levels, unintended chemical and physical contaminants, and ingredients of inappropriate quality.
684. Bacteria and fungus are among the impurities commonly found in compounded injectable drugs, including the drugs identified in the Execution Protocol.
685. Bacterial and/or fungal contamination will alter important attributes of the compounded execution drugs used in Plaintiff's execution, including the final pH.
686. There is a substantial risk that alteration of the final pH of the compounded execution drugs used in Plaintiff's execution will create instability and/or incompatibility with human blood.

687. There is a substantial risk that, should the pH of the compounded execution drugs used in Plaintiff's execution be incorrect, Plaintiff will experience a burning sensation as it is being injected.
688. There is a substantial risk that, should the pH of the compounded execution drug(s) used in Plaintiff's executions be incorrect, it could form precipitates, or solid particles, of drug and other substances.
689. Contamination with particulate matter is also common in compounded injectable drugs.
690. Should solid, particulate matter of any kind be present in the compounded execution drug(s) used to execute Plaintiff, there is a substantial risk that Plaintiff will suffer unnecessary pain and suffering upon injection of the solution, including, but not limited to, the pain associated with a pulmonary embolism.
691. Bacterial and/or fungal contamination in compounded injectable solution produces endotoxins and/or exotoxins.
692. Endotoxins and/or exotoxins contained in compounded injectable solution can cause immediate and painful reactions associated with septic shock, including, but not limited to, a sudden rise in body temperature, a precipitous drop in blood pressure and seizure.
693. Should endotoxins and/or exotoxins be present in the compounded execution drug(s) used to execute Plaintiff, there is a substantial risk that Plaintiff will suffer unnecessary pain and suffering upon injection of the solution.

694. Bacteria and/or fungi commonly found in compounded injectable solution are growing organisms.
695. The presence of growing organisms accelerates chemical degradation.
696. Chemical degradation decreases the potency of injectable solutions such as pentobarbital and thiopental sodium.
697. Should bacterial and/or fungal contamination reduce the potency of the execution drug(s) used to execute Plaintiff, there is a substantial risk Plaintiff will not receive an adequate dose of the execution drug, thereby inflicting unnecessary pain.
698. The analytical testing provision in the Execution Protocol, stating that a sample of compounded execution drugs will be tested for potency and identity, will not resolve this problem.
699. That testing will be done (according to the Execution Protocol) approximately 30 days before execution, leaving plenty of time between the testing date and the execution date for continued growth of bacterial and/or fungal contamination and thereby continued reduction in potency of the drug between testing date and execution date.
700. The testing for potency and identity will not detect the presence of contaminants which would alert Defendants that, even though the potency standards might be sufficient 30 days in advance of the execution date, the compounded drug's potency will be reduced by the time the execution date arrives.

701. FDA inspections of some Ohio compounding pharmacies over recent years have resulted in warning letters identifying numerous deviations from relevant regulations and established Good Manufacturing Practices which resulted in the distribution of drugs that were adulterated, including deviations such as failure to monitor and validate the manufacturing process, and a failure to reject product that was found to be incorrect in identity, strength, quality and/or purity.
702. The Execution Protocol does not ensure the receipt, storage, control and distribution of any compounded execution drugs only in the full and actual charge of an appropriately licensed health care professional.
703. The Execution Protocol, by its terms, allows receipt, storage, control and distribution of any compounded execution drug(s) by the Warden and the Drug Administrators, *i.e.*, persons other than an appropriately licensed health care professional, in violation of the relevant federal and State of Ohio laws.
704. The Execution Protocol contains no provision requiring the proper storage or verification of “beyond use” dates for any compounded execution drugs that might be used for an execution.

705. The problems with the lack of FDA oversight of compounding came to national attention following the tragic event in 2012 when a compounding pharmacy providing medical facilities in 20 states with compounded steroid injections contaminated with fungal meningitis, which resulted in 64 patients dying, with a total of 751 patients falling ill after injection with the compounded drugs. See Centers for Disease Control and Prevention, *Multistate Outbreak of Fungal Meningitis and Other Infections* (Oct. 23, 2013).⁷
706. As a result of the events of 2012, the FDA inspected some sterile compounding facilities and found serious quality-control problems, resulting in contaminated products. “Numerous recalls of sterile products have been conducted, and numerous pharmacies chose to stop sterile compounding after [the FDA] identified problems with their sterile compounded processes.” See FDA, *Compounding—FDA Implementation of the Compounding Quality Act*.⁸

⁷ Available at <http://www.cdc.gov/hai/outbreaks/meningitis.html>.

⁸ Available at <http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmaceuticalcompounding/ucm375804.htm>.

707. In addition, the five main testing facilities used by 90% of all the nation's large-scale compounding pharmacies in order to verify the strength, sterility, and purity of the compounding drugs were inspected by the FDA shortly after the October 2012 incident. See Kimberly Kindy, *Labs that test safety of custom-made drugs fall under scrutiny*, WashingtonPost.com, Oct. 5, 2013, available at 2013 WLNR 24973227.
708. Those labs were cited for more than 70 safety problems, including lack of sterile facilities and scientifically unsound testing. *Id.*
709. Various Ohio compounding entities have been found to have engaged in significant deviations from the applicable federal laws in ways that would constitute significant constitutional problems if done as part of the Execution Protocol.
710. Without FDA approval of a drug and its manufacturing process, there is no reasonable assurance that the drug has the identity, purity, potency, and efficacy that it is represented to have. See Sellers & Utian, *Pharmacy Compounding Primer for Physicians: Prescriber Beware*, *supra*, at 2048.
711. With compounded drugs, there is a substantial risk that excipient (inactive) ingredients and APIs will be obtained from non-FDA-approved sources.

712. Compounding pharmacies are substantially likely to obtain the API for compounding any of the execution drugs in the Execution Protocol from companies in India or China or Pakistan, or other overseas companies that are not registered with or inspected by the FDA.
713. The API provided by these sources is highly suspect and there is no practical method to verify their quality, constitution, or uniformity in limited pharmacy settings such as retail compounding pharmacies.
714. The sources from which compounding pharmacies obtain the API's for their drug concoctions are often part of the global grey market, which is one of the leading sources for counterfeit drugs entering the United States.
715. In the unregulated market of APIs, a chemical labeled to represent a certain active ingredient may not actually contain the correct ingredient and it may contain harmful contaminants.
716. There is a substantial risk that Defendants will use execution drugs manufactured by any of the Drug Source Defendants that compounded APIs obtained from non-FDA-registered facilities, *i.e.*, on the grey market.
717. There is a substantial risk that the APIs obtained on the grey market in order to compound drugs for use in the Execution Protocol are impure, adulterated, sub-potent, and/or counterfeit.

718. There is a substantial risk that grey market APIs will come from plants in China, India, and/or other countries lacking the oversight and control necessary to produce uncontaminated, unadulterated, fully potent, and genuine APIs.
719. Plants in China providing APIs to the grey market have manufactured pesticides using the same equipment that is used to make APIs.
720. Several studies, including a survey conducted by the FDA in 2001, report a high prevalence of quality problems with various pharmacy-compounded drugs, including sub-potency and contamination.
721. A survey of compounded drug products was conducted by the FDA in 2006 to explore these issues further. The results showed that thirty-three percent of the compounded drugs failed analytical testing using rigorously defensible testing methodology.
722. A thirty-three percent quality failure rate of compounded drugs constitutes a substantial risk of harm.
723. Testing by the Missouri Board of Pharmacy, which is the only state that regularly tests compounded drugs, reveals that compounded drugs fail tests for potency and purity on average around twenty-five percent of the time.
724. A twenty-five percent quality failure rate of compounded drugs constitutes a substantial risk of harm.

725. Pentobarbital and the other drugs in the Execution Protocol can be difficult to compound to the precise tolerances necessary to prevent an improper buffering (pH) level or to prevent the compounded drug from falling out of solution/precipitating.
726. Injecting a compounded solution that is buffered to the incorrect pH level will cause extremely painful burning upon coming into contact with human blood.
727. Injecting a drug that has precipitated or that will precipitate inside the recipient will cause the insides of the recipient's veins to feel burning, extremely painful sensations as if they are being scraped with sandpaper.
728. The chance of precipitation of compounded execution drugs is substantial at the least. For example, the solvent used in the typical formation of compounded pentobarbital is a water, propylene glycol, alcohol mixture (in a 50-40-10 ratio). The presence of the propylene glycol and alcohol suggest that pentobarbital sodium is not completely water soluble. This means if the compounded execution drug is mixed with additional water (thus diluting the alcohol and the propylene glycol), the pentobarbital will likely fall out of solution/precipitate, producing crystals of the drug floating in the container.

729. Because blood is essentially water, injecting the compounded pentobarbital rapidly, as DRC Drug Administrators do, will result in the drug precipitating in the vein, causing significant pain to the recipient.
730. Only a few other states have used compounded drugs in executions, and their experiences demonstrate that the use of compounded execution drugs makes it sure or very likely that that the inmate will suffer severe, unnecessary and inhumane pain and a lingering death.
731. Defendants are unable to reduce said substantial risk or have made it even greater because: (a) the manufacturer(s) of the APIs is/are unknown; (b) the impurity profiles of the APIs are unknown; (c) the age, storage, the manufacturing environment, or the manufacturing method of the APIs are unknown; (d) Defendants want to hide the identity of the compounding pharmacy and compounding pharmacist; and (d) Defendants want to hide the identity of any laboratory that conducts any analytical testing of the finished drug product under the Execution Protocol.
732. Within the grey market, secondary sources of APIs, *e.g.*, wholesalers and/or distributors, frequently use ambiguous and/or false statements in marketing APIs.
733. Statements from such secondary sources provide no reliable assessment of the purity, potency, identity, and/or lack of contamination of grey market APIs.

734. Intrinsic or extrinsic contaminants can be introduced during chemical manufacture or at any point during the chemical's synthesis.
735. Even if the API obtained and used by any Drug Source Defendants is not counterfeit and is domestically produced, there is a significant chance that it could be contaminated, adulterated, hyperpotent or hypopotent, the improper concentration, non-sterile, or myriad other characteristics creating a substantial likelihood that the drug(s) is not the execution drug(s) mandated by Core Element # 2, and a substantial likelihood that the lethal injection process could be extremely painful, or harm or handicap Plaintiff without actually killing him.
736. There is a substantial risk that Defendants will not identify the presence of harmful contaminants in compounded execution drugs that pose an immediate safety threat if administered intravenously.
737. Defendants, including, but not limited to, the Drug Source Defendants, do not have the ability to trace the APIs back to the original manufacturers for information on quality, packaging, storage, shipment conditions and chains of custody from a chemical's cradle to grave.
738. The Execution Protocol contains no express provision by which Defendants will ensure that the raw API in any compounded execution drug is not imported, is sterile, is unadulterated, is not

- contaminated, or is otherwise anything other than pure raw API for the specific execution drug.
739. Testing drugs after they have been compounded does not compensate for the absence of reliable, FDA-approved raw materials obtained from reputable, ethical, duly registered suppliers because post-compounding testing alone is not designed to ensure sterility or purity.
740. Any analytical testing results are invalid without any accompanying information about the testing protocols the testing facility employed, as well as information about the testing facility itself. The facility, its employees, its protocols, its procedures, its API sources and more must be fully vetted before any analytical testing results might be considered valid.
741. The United States Pharmacopeia and The National Formulary (USP-NF) General Chapter 797 provides the standards that pharmacies compounding sterile dosage forms of drugs (also referred to as compounded sterile preparations or CSPs), such as injectables like the drugs in the Execution Protocol, are supposed to follow. See USP-NF Gen'l Ch. 797: Pharmaceutical Compounding—Sterile Preparations (June 2014).
742. Any compounded execution drugs DRC Defendants would acquire from Drug Source Defendants would be derived from non-sterile API, and thus under USP-NF General Chapter 797 would be high-risk-level

CSPs. See USP-NF Gen'l Ch. 797: Pharmaceutical Compounding—Sterile Preparations (June 2014).

743. Although all pharmacies performing sterile compounding are supposed to follow USP-NF General Chapter 797, there is a lack of enforcement of these standards. The FDA defers enforcement of USP-NF General Chapter 797 to individual states. Jennifer Gudeman et al., *Potential Risks of Pharmacy Compounding*, Drugs in R&D vol. 13, iss. 1, at 3 (Mar. 23, 2013).
744. Only a handful of states have fully incorporated USP-NF General Chapter 797 into their regulations, and it is unclear whether any states have conducted, much less regularly conduct, inspections of any compounding pharmacies that sell CSPs to assure that they are in compliance with USP-NF General Chapter 797. See *id.*
745. The Ohio State Board of Pharmacy has incorporated USP-NF General Chapter 797 fully into its regulations, effective on January 1, 2015. See Ohio Admin. Code § 4729-9-21(C)(2) (eff. Jan. 1, 2015).
746. Accordingly, strict compliance with USP <797> is now required for an Ohio-licensed compounding pharmacy.
747. Defendants Pharmacies # 1–100 and Defendants Pharmacists # 1–100 violate the law when they fail to fully comply with USP <797>. And Defendants will deviate from the Core Elements of the Execution Protocol if Drug Source Defendants violate the law by failing to fully comply with USP <797>.

748. If the pharmacy is a “non-resident” pharmacy—that is, it is a pharmacy located outside of Ohio—then the Ohio State Board of Pharmacy relies on the other state’s board of pharmacy to inspect and enforce regulations. See Ohio Admin. Code § 4729-10-04. But again, other states might not require adherence to USP-NF General Chapter 797, much less regularly inspect pharmacies for compliance. See Isaac Cohen, M.D., Isaac Cohen, MD, Rebuts—*Compounding Pharmacies: A Viable Option, or Merely a Liability*, Am. Academy of Phys. Med. & Rehab. 974, 980 (Nov. 2013).
749. Even if compounding pharmacies do actually follow USP-NF General Chapter 797 standards, those standards are less stringent, and produce less reliable drugs, than the FDA Good Manufacturing Practices. Jennifer Gudeman et al., *Potential Risks of Pharmacy Compounding*, *supra*, at 4 (comparing the failure rate of <2% for 3,000 FDA-approved commercial products tested from 1996 to 2001 to the failure rates ranging from 11% to 34% for compounded drugs randomly tested by the FDA, Missouri, and Texas).
750. Drugs compounded in accordance with USP-NF General Chapter 797 have a low standard of sterility assurance compared to the FDA standard. *Id.* (“USP <797> does not afford the same degree of sterility assurance for compounded drugs that GMPs provide for FDA-approved sterile products”).

751. There is a substantial risk of harm from Defendants' use of unverified ingredients, including the administration of an entirely incorrect chemical or active ingredient, administration of sub- or super-potent execution drugs, contamination with dangerous allergens or substances that may cause immediate anaphylactic reactions, and/or contamination with bacteria or fungus with immediate excruciating effects before Plaintiff is unconscious, unaware and insensate, assuming it works even to that extent.
752. Even if the anesthetic drug is fully or partially effective, compounded drugs can cause serious harm and severe pain before loss of consciousness, awareness, and sensation.
753. Such harms include painful pulmonary embolisms resulting from deviations in potency or formation of precipitates within the body or from unanticipated drug incompatibilities; partial or complete lack of effect due to ingredient tampering; nausea and vomiting resulting from deviations in potency; suffocation and gasping for breath; immediate anaphylactic reactions or other excruciating effects resulting from contamination with dangerous allergens, bacteria, fungus, or other impurities; and serious burning pain on injection, as a result of incorrect pH and/or the drug precipitating inside Plaintiff's veins.

754. All of these circumstances would be expected to prolong the execution, make it a lingering death and a spectacle execution, and to multiply the pain and suffering beyond the objective of causing death.
755. Defendants' use of compounded—as opposed to manufactured, FDA-approved—drugs in executions makes it sure or very likely that the drug will be the wrong identity or pH level, prone to falling out of solution/precipitating, ineffective, sub-potent, contaminated, unsterile, or otherwise adulterated.
756. It is sure or very likely that compounded execution drugs will be made using poor quality practices, and will not be the incorrect identity, not buffered to the correct pH level, prone to falling out of solution/precipitating, ineffective, sub-potent, contaminated, unsterile, or otherwise adulterated.
757. Defendants' use of compounded drugs in executions makes it highly likely that Defendants will deviate from Core Elements of the Execution Protocol, and/or will apply the law disparately to similarly situated inmates, arbitrarily and recklessly.
758. Testing a sample of one solution made of a compounded drug, as Defendants' Execution Protocol calls for, is not reliable as to the identity, sterility, potency, or efficacy of the solution as a whole.
759. Similarly, testing one solution of several made of a compounded drug is not reliable as to the identity, sterility, potency, or efficacy of the other solutions made.

760. The risks associated with using execution drugs that are compounded in general are significantly enhanced by the risks associated with compounding performed by particular Drug Source Defendants.
761. Upon information and belief, Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 are ill-equipped and lacking the expensive equipment necessary to compound sterile injectables.
762. Upon information and belief, Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 are not possessing of the required high degree of skill, experience and training necessary to compound sterile injectables.
763. Upon information and belief, Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100, are ethically compromised and thus substantially likely to overlook contaminants or other of the myriad problems associated with compounded sterile controlled substances.
764. Upon information and belief, Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 are aware of and take offense at Plaintiff's crime of conviction.
765. Upon information and belief, Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 know that what little oversight will be employed regarding the compounded execution drugs they concoct will be limited to identity and potency.

766. Upon information and belief, Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 believe that Ohio state law provides blanket secrecy protection against any professional or legal ramifications for any harm done to Plaintiff by compounded execution drugs.
767. Thus, upon information and belief, it is sure or very likely that Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 will include unknown and/or undetectable substances or materials in the compounded drugs to cause Plaintiff great suffering and pain upon injection.
768. Accordingly, by DRC Defendants obtaining a particular batch of compounded execution drugs from Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 to be used for Plaintiff or others who immediately follow on Defendants' execution schedule, there is a risk of harm that is even greater than the ordinary, sure or very likely harm from using compounded execution drugs in general.
769. As with any matter involving the exercise of judgment and professional skill, the viability of drugs manufactured via compounding is dependent upon the skill, expertise, and judgment of the compounder, i.e., the Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100.

770. And, in that sense, the Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 are as essential to Defendants' administration of the Execution Protocol as the Execution Team members, the Medical Team, the Drug Administrators, the Director, the SOCF Warden, the CCI Warden, or any other actors involved in any way in carrying out an execution.
771. Indeed, the professional contributions of the Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 are just as important to the successful completion of an execution in a constitutional manner as that of any of the Execution Team members or other actors involved, including the Medical Team and Drug Administrators, the Director, and the Warden, if not more so.
772. Upon information and belief, Defendant Kasich has endeavored to shut down all state audits of private contractors until the end of his second term in office, see Janet Reitman, *Where the Tea Party Rules*, ROLLING STONE, Oct. 14, 2014,⁹ thereby potentially ensuring that there will be no state audit of Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100.
773. Amendments to the Ohio Revised Code sought by Defendants and counsel for Defendants and signed into law by Defendant Kasich after

⁹ Available at <http://www.rollingstone.com/politics/news/where-the-tea-party-rules-20141014>.

an expedited process in a lame-duck legislative session, Ohio Rev. Code §§ 2929.221–.222, attempt to keep secret the identity of any Drug Source Defendants, including Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100, thereby eliminating any meaningful, independent oversight of Defendants as it relates to execution matters, including matters related to the execution drugs.

774. The omission of any such oversight, redundancies, and other reviews and checks as to the Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 has created a blind spot in the execution process, one which enables any Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100 who might be unscrupulous, corrupt, and/or incompetent to intentionally or unintentionally subvert the process, as a result of negligence but also as a result of malice.

775. It is sure or very like that compounded drugs used in the execution of Plaintiff will be defective in one or more of the following respects:

- a) the compounded execution drugs are not what they purport to be and are not the drug(s) required by the written execution protocol;
- b) the compounded execution drugs will not be the requisite potency and concentration for the intended usage, nor the potency and concentration required by the Execution Protocol;
- c) the compounded execution drugs are contaminated (such as with impurities or other drugs), are adulterated such as with other substances that would make the execution painful, are

not sterile to the same degree as manufactured by a reliable manufacturer making an FDA-approved product;

- d) the compounded execution drugs are not fit for their intended usage; and/or
- e) the compounded execution drugs have not been manufactured, compounded, produced, procured, conveyed, stored, handled, and dispensed in strict compliance with all applicable Ohio and federal statutes, regulations, or other laws or requirements.

776. Moreover, because they have omitted any oversight, redundancies, and other reviews and checks on the manufacturing facilities and/or work product of the Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100, the DRC Defendants will not determine in advance, if ever, whether a particular execution has been plagued or is about to be plagued by the negligence, incompetence, and/or malice of the Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100, including, for example, by the use of compounded execution drugs which include substances that intentionally or unintentionally cause the target of a particular execution to suffer something worse than the humane and dignified death to which he is entitled.

777. Because no one is exercising oversight or otherwise reviewing the manufacturing facilities and/or work product of the Defendants Unknown Pharmacies #1–100 and Defendants Unknown Pharmacists #1–100, there is nothing to prevent such error or malfeasance from occurring and, what is just as bad, there is nothing to provide assurance to the intended target of the compounded execution drugs

that such error or malfeasance cannot and will not occur in his execution.

778. Defendants knew or should have known each fact alleged herein and they have acted and/or continue to act, with deliberate indifference to the same.

I. Allegations related to imported execution drugs.

779. Using imported execution drugs creates a substantial risk of serious harm to Plaintiff, because it is sure or very likely that such drugs are contaminated, adulterated, not of the correct identity, super- or sub-potent, or in myriad other ways not identical in make and quality to domestically produced execution drugs, because imported execution drugs have not been subject to the same stringent quality and manufacturing standards to which domestically produced drugs are subjected. Accordingly, it is sure or very likely that Plaintiff will be subjected to severe harm, including serious physical and/or mental or psychological pain and suffering, a lingering death, a spectacle execution that is not dignified, and other risks that are objectively intolerable but which Defendants ignore.
780. Imported thiopental sodium is, by definition, not ensured to be safe and effective because, as an unapproved drug, FDA have never found *any* thiopental sodium to be safe and effective.
781. Drugs to be used for an execution may not be lawfully exported to the United States from any European Union country.

782. Thus, any drugs to be used by DRC Defendants to carry out an execution under the Execution Protocol are likely to originate in third-world countries or countries without rigorous drug-manufacturing oversight, or exported from a European Union country illegally.
783. Upon information and belief, drugs to be used for an execution that are manufactured overseas and exported to the United States by Drug Source Defendants have not been manufactured in an FDA-registered and –inspected facility under quality assurance procedures designed to produce a safe and effective product, such as current Good Manufacturing Practices.
784. Upon information and belief, drugs to be used for an execution that are manufactured overseas and exported to the United States by Drug Source Defendants have not been shipped, handled, and stored under conditions that meet U.S. requirements to ensure the drugs' safety and effectiveness.
785. Upon information and belief, drugs—and their ingredients—to be used for an execution that are manufactured overseas and exported to the United States by Drug Source Defendants have not been evaluated for safety and effectiveness with the same level of oversight used for drug approval in the United States.
786. Upon information and belief, drugs to be used for an execution that have been manufactured overseas and exported to the United States

by Drug Source Defendants do not contain all the required labeling information.

787. Upon information and belief, drugs to be used for an execution that have been manufactured overseas and exported to the United States by Drug Source Defendants do not contain accurate, reliable labeling information, calling into question matters such as the true identity of a particular drug, and that drug's contents.
788. Upon information and belief, drugs to be used for an execution that are manufactured overseas and exported to the United States by Drug Source Defendants are not manufactured to the tolerances required by the USP (United States Pharmacopeia).
789. Upon information and belief, such drugs were manufactured to the lower tolerances contained in the IP (Indian Pharmacopeia), the EUP (European Union Pharmacopeia) or the BP (British Pharmacopeia).
790. Under the IP, EUP and BP monographs for formulation of thiopental sodium, the API must be a minimum of 84% thiopental content and 10.5% sodium content, which is mixed with 6% sodium carbonate.
791. Under the USP monograph, however, the API for thiopental sodium must be minimum 98% thiopental sodium (*i.e.*, not mixed with carbonate).
792. Analytical testing of any imported execution drugs is not required by Defendants' Execution Protocol.

793. Any discretionary analytical testing performed on imported execution drugs will be subject to the same fundamental problems and flaws identified above relating to analytical testing of Defendants' compounded execution drugs.
794. Defendants' use of imported drugs in executions makes it sure or very likely that the drug will be the wrong identity or pH level, the incorrect concentration, ineffective, sub-potent, super-potent, contaminated, unsterile, or otherwise adulterated or misbranded.
795. It is sure or very likely that imported execution drugs will be made using poor quality practices, and will be the incorrect identity, the incorrect concentration, not buffered to the correct pH level, ineffective, sub-potent, super-potent, contaminated, unsterile, or otherwise adulterated or misbranded.
796. The use of imported drugs in executions makes it highly likely that Defendants will deviate from the Core Elements of the Execution Protocol and/or will apply the law disparately to similarly situated inmates, arbitrarily and recklessly.
797. Except for exceptions not applicable here, it is unlawful to import into the United States, and the FDA is required to refuse admission of, any misbranded or unapproved drugs. *Cook v. FDA*, 733 F.3d 1, 3 (D.C. Cir. 2013) (citing 21 U.S.C. § 381(a)).
798. A drug is "misbranded" under federal law if "it was 'manufactured, prepared, propagated, compounded, or processed in an establishment

not duly registered' with the FDA." *Cook*, 733 F.3d at 3 (quoting 21 U.S.C. § 352(o)).

799. Upon information and belief, any execution drugs Drug Source Defendants intend to import or have imported to provide to DRC Defendants to use in a lethal-injection execution will not come from an FDA-registered facility, rendering such execution drug(s) "misbranded" and therefore unlawful to import into the United States. Imported thiopental sodium will also be misbranded under federal and state law for the reasons identified herein.
800. Thiopental sodium is an unapproved new drug that may not be lawfully introduced into interstate commerce under 21 U.S.C. § 355(a), because it is no longer "generally recognized, among experts . . . as safe and effective" for its labeled use, [21 U.S.C.] § 321(p)(1)." See *Cook*, 733 F.3d at 3–4 (explaining that "[a]lthough thiopental has been used as an anesthetic since the 1930s, it is presently an unapproved new drug").
801. Likewise, thiopental sodium is an unapproved new drug because "it is undisputed that the FDA has *never* approved or even reviewed" thiopental (imported or manufactured domestically) "for safety and effectiveness" under 21 U.S.C. § 355(d). *Beaty v. FDA*, 853 F. Supp. 2d 30, 34–35 & n.2 (D.D.C. 2012), affirmed in relevant part sub. nom., *Cook*, 733 F.3d at 3–4.

802. Pentobarbital, midazolam, the paralytic drug, and potassium chloride are each an unapproved new drug as to their respective use for executions, because none of those drugs has ever been approved for use as an execution drug nor have any of those drugs ever been the subject of an Investigational New Drug application (either filed or granted).
803. Under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 381(a), and the Administrative Procedure Act (APA), 5 U.S.C. § 706(2)(A), the FDA is required to refuse admission to thiopental sodium shipments coming into the United States. *See Cook*, 733 F.3d at 10–11.
804. Under *Cook* and the relevant provisions of federal law, importing thiopental sodium into the United States is prohibited, and thus Defendants may not legally import thiopental sodium to use for an execution.
805. Upon information and belief, however, Defendants have taken actions to try to import thiopental sodium, despite being on notice that such imports are illegal.
806. Those actions generated a letter to DRC Director Gary Mohr from Captain Domenic J. Veneziano, the Director of the Division of Import Operation, United States Public Health Service, which is part of the FDA.

807. In that letter, dated June 26, 2015, Captain Veneziano reiterated to Director Mohr that the permanent injunction entered in *Beaty* enjoins FDA “from permitting the entry of, or releasing any future shipments of, foreign manufactured sodium thiopental that appears to be misbranded or an unapproved new drug in violation of 21 U.S.C. § 355. Please note that there is no FDA approved application for sodium thiopental, and it is illegal to import an unapproved new drug into the United States.” Letter from Domenic J. Veneziano, Dir., Div. of Import Operation, U.S. Public Health Serv., Food and Drug Admin., Dep’t of Health and Human Serv., to Gary C. Mohr, Dir., Ohio Dep’t of Rehab. and Corr. (June 26, 2015), available online at Alan Johnson, *FDA warns Ohio not to illegally import execution drugs*, COLUMBUS DISPATCH, Aug. 19, 2015¹⁰; see also Chris McDaniel, *Ohio Intended To Illegally Import Execution Drugs, FDA Letter Says*, BUZZFEED NEWS (Aug. 18, 2015, 7:19 PM).¹¹

808. Even after being explicitly told by the FDA that importation of thiopental sodium is illegal, Defendants have taken further actions such as updating DRC’s DEA registration to import thiopental

¹⁰ Available at <http://www.dispatch.com/content/stories/local/2015/08/19/FDA-letter-ohio-execution-drugs.html>.

¹¹ Available at <http://www.buzzfeed.com/chrismcdaniel/ohio-intended-to-illegally-import-execution-drugs-fda-letter#.iyEJXQjX2>.

- sodium, and sending a responsive letter on October 9, 2015 to the FDA insisting that Ohio can, indeed, legally import thiopental sodium. Letter available online at Chris McDaniel, *Ohio Insists It Can Import Execution Drug Legally, After FDA Said It Couldn't*, BUZZFEED NEWS (Oct. 9, 2015).¹²
809. Federal law, *see, e.g.*, 21 U.S.C. §§ 952(a), 957, 958, also establishes that any attempt by Defendants to import pentobarbital or midazolam to use for executions would be illegal, and DEA should seize such imports, because DRC Defendants do not possess the required DEA registration to legally import pentobarbital or midazolam.
810. Federal law also establishes that if any person such as any Drug Source Defendant manufactures or distributes pentobarbital or midazolam intending or knowing that the drugs will be unlawfully imported into the United States, that person is also violating the Controlled Substances Act. 21 U.S.C. §§ 959, 960.
811. Federal law prohibits knowingly or intentionally furnishing false or fraudulent information in the documentation required to be permitted to import controlled substances. *See, e.g.*, 21 U.S.C. § 843(d); 19 U.S.C. §§ 1592, 542.

¹² Available at https://www.buzzfeed.com/chrismcdaniel/ohio-insists-it-can-import-execution-drug-legally-after-fda?utm_term=.gxp9Qa7vo#.bdzAJm1XE.

812. Upon information and belief, Defendants will not be permitted to import execution drugs unless Defendants or their agents provide false or fraudulent information regarding the attempted importation; there is no authorization for Defendants or their agents to import pentobarbital or midazolam, and thiopental sodium may only be imported in limited situations that are not applicable to the execution context.
813. Thus, any import of pentobarbital or midazolam by Defendants to use for executions would be necessarily based on fraudulent or false information.
814. Similarly, any importation of thiopental sodium by Defendants to use for executions would require providing false or fraudulent information to fraudulently invoke one of the limited exceptions for importing that drug.
815. Further, upon information and belief, Defendants or their agents provided false or fraudulent information in the course of applying for, and obtaining, a DEA Controlled Substance Registration for importing thiopental sodium, and by seeking a DEA Controlled Substance Registration for importing pentobarbital, by representing that procurement of execution drugs will be only in accordance with all applicable State and Federal Laws, licensing authorities, and ODRC policies and procedures.

816. Defendants have been on notice that predates DRC Defendants' application for the import registrations that procuring the controlled substances to use for an execution under Ohio's Execution Protocol is impossible to do while remaining compliant with all applicable Ohio and federal laws, licensing authorities, and/or ODRC policies and procedures.

J. Additional allegations regarding Ohio state law.

817. It is a crime under Ohio state law for a person to knowingly obtain, possess, or use a controlled substance. Ohio Rev. Code § 2925.11(A). If one is a drug manufacturer, licensed health professional authorized to prescribe drugs, pharmacist, owner of pharmacies, or any other person who performs these actions in compliance with Ohio Revised Code Chapter 3719, 4715. 4723, 4729, 4730, 4731 and 4741, subsection (A) does not apply. Ohio Rev. Code § 2925.11(B)(1).

818. If one is a person who obtained the controlled substance pursuant to a lawful prescription issued by a licensed health professional authorized to prescribe drugs, subsection (A) does not apply. Ohio Rev. Code § 2925.11(B)(4).

819. Otherwise, whoever knowingly obtains, possesses, or uses a controlled substance is guilty of a felony of varying degree ranging from first to fifth depending on the amount of the drug involved. Ohio Rev. Code § 2925.11(C).

820. It is a crime under Ohio state law for any person to deceive another to procure the administration of, a prescription for, or the dispensing of, a dangerous drug. Ohio Rev. Code § 2925.22(A). Whoever commits such an Ohio crime is guilty of a felony of varying degree ranging from first to fifth. Ohio Rev. Code § 2925.22(B).
821. It is a crime under Ohio state law for a person by force, threat, or deception, administer to another or induce or cause another to use a controlled substance. Ohio Rev. Code § 2925.02(A)(1).
822. It is also a crime under Ohio state law for a person to, by any means, administer or furnish to another or induce or cause another to use a controlled substance, and thereby cause serious physical harm to the other person. Ohio Rev. Code § 2925.02(A)(3).
823. If the person who administers a controlled substance to another or induces or causes another person to use a controlled substance is a drug manufacturer, wholesaler, licensed health professional, pharmacist, pharmacy or any other person who performs these actions in compliance with Ohio Revised Code Chapter 3719, 4729, 4730, 4731 or 4741, subsections (A)(1) and (A)(3) do not apply.
See Ohio Rev. Code § 2925.02(B).
824. Otherwise, however, whoever commits any of these actions is guilty of a felony of varying degree ranging from first to fifth degree. Ohio Rev. Code § 2925.02(C).

825. It is a crime under Ohio state law for a person to, by any means, administer or furnish to another or induce or cause another to use a controlled substance with purpose to cause serious physical harm to the other person. Ohio Rev. Code § 2925.02(A)(2). There is no exception to this criminal law, and whoever commits any of these actions is guilty of a felony of varying degree ranging from first to fifth degree. Ohio Rev. Code § 2925.02(C). If the controlled substance in question is a schedule II or schedule III drug, the crime is a second degree felony. Ohio Rev. Code § 2925.02(C)(1)(a), (C)(2)(b).
826. It is a crime under Ohio state law for any person, other than for lawful research, clinical, medical, dental or veterinary purposes, to obtain, possess or use a harmful intoxicant with the purpose to induce intoxication or similar physiological effects. Ohio Rev. Code § 2925.31(A). Whoever commits such an Ohio crime is guilty of a first-degree misdemeanor, unless the person has previously been convicted of a drug abuse offense, in which case violating § 2925.31(A) is a fifth-degree felony.
827. It is a crime under Ohio state law for any person to knowingly dispense or distribute a harmful intoxicant to a person age eighteen or older if the person who dispenses or distributes it knows or has reason to believe that the harmful intoxicant will be used in violation of section 2925.31 of the Revised Code. Ohio Rev. Code § 2925.32(A)(1). Whoever commits such an Ohio crime is guilty of a

- fifth-degree felony, or a fourth degree felony if the person has previously been convicted of a drug abuse offense. Ohio Rev. Code § 2925.32(D)(1).
828. It is a crime under Ohio state law for any person to sell, deliver, offer for sale, hold for sale, or give away any new drug unless an application with respect to the drug has become effective under 21 U.S.C. § 355. Ohio Rev. Code §§ 3715.65(A), 3715.99(D). Whoever commits such an Ohio crime is guilty of a fourth degree misdemeanor for the first offense, and guilty of a second degree misdemeanor for each subsequent offense. Ohio Rev. Code § 3715.99(D).
829. It is a crime under Ohio state law for any person to engage in Prohibited Acts as defined in Ohio Revised Code §§ 3715.52(A), 3715.99(D). Thus, it is a crime under Ohio state law to manufacture, sell, deliver, or hold or offer for sale any drug that is adulterated or misbranded, Ohio Rev. Code § 3715.52(A)(1), or to adulterate or misbrand any drug, Ohio Rev. Code § 3715.52(A)(2), or to receive in commerce any drug that is adulterated or misbranded and the delivery or proffered delivery of any adulterated or misbranded drug, for pay or otherwise, Ohio Rev. Code § 3715.52(A)(3). Whoever commits any of these Ohio crimes is guilty of a fourth degree misdemeanor for the first offense, and guilty of a second degree misdemeanor for each subsequent offense. Ohio Rev. Code § 3715.99(D).

830. It is a crime under Ohio state law for an Ohio law enforcement official to negligently fail to prevent or halt the commission of an Ohio crime; for an Ohio law enforcement, ministerial, or judicial officer to negligently fail to perform a lawful duty in a criminal case or proceeding; for a public official to recklessly fail to perform a duty expressly imposed by law with respect to the public servant's office; or a public official to do an act expressly forbidden by law with respect to the public servant's office. *See* Ohio Rev. Code § 2921.44(A)–(E). Whoever commits any of these actions is guilty of a misdemeanor of the second degree. *See* Ohio Rev. Code § 2921.44(F).
831. It is a crime under Ohio state law for any person to knowingly use or rely on an instrument that is not lawfully issued to assert jurisdiction over or determine the legal or equitable status, rights, duties, powers, or privileges of any person or property or to knowingly commit or facilitate the commission of a crime or for purposes of committing a felony. *See* Ohio Rev. Code §2921.52(B)(3)–(4). Whoever commits any of these actions is guilty of a felony in the third or fourth degree. *See* Ohio Rev. Code § 2951.52(D).
832. Pursuant to Ohio Revised Code § 2921.45, no public servant, under color of his office, employment, or authority, shall knowingly deprive, or conspire or attempt to deprive any person of a constitutional or statutory right. Whoever commits such actions is guilty of a misdemeanor of the first degree.

833. It is a crime under Ohio state law for any person employed by, or associated with, any enterprise to conduct or participate in, directly or indirectly, the affairs of an enterprise through a pattern of corrupt activity. Ohio Rev. Code § 2923.32(A)(1). Whoever commits any of these actions is guilty of a felony in the second degree, or potentially the first degree. Ohio Rev. Code § 2923.32(B)(1).
834. It is a crime under Ohio state law for any person who has knowingly received any proceeds derived, directly or indirectly, from a pattern of corrupt activity to use or invest, directly or indirectly, any part of those proceeds, or any proceeds derived from the use or investment of any of those proceeds, in the acquisition of any title to, or any right, interest, or equity in, real property or in the establishment or operation of any enterprise. Ohio Rev. Code § 2923.32(A)(3). Whoever commits any of these actions is guilty of a felony in the second degree, or potentially the first degree. Ohio Rev. Code § 2923.32(B)(1).

K. Allegations related to the definitions of “Director” and “Warden” in the Execution Protocol

835. The Execution Protocol allows the DRC Defendants by its terms—and the Drug Supplier Defendants by implication—to deviate/vary from the written protocol if for any reason it is difficult, impractical or impossible to strictly follow the procedures in the written protocol.

836. The Execution Protocol also allows the DRC Defendants by its terms, and the Drug Supplier Defendants by implication, to deviate/vary from the written protocol if any situation arises that would make strictly following the written protocol difficult, impractical or impossible.
837. The Execution Protocol requires that any variation of a “substantial nature” must be approved by the Director of DRC.
838. A previous written execution protocol, effective September 18, 2011, required that *only* the Director of DRC may authorize a variation from the mandates of the written protocol, and this Court previously rejected motions for injunctive relief on the basis that the evidence demonstrated that all deviations from the execution protocol would flow to one person, and one person only—only the Director of DRC—and only that single person could authorize deviations, thus ensuring strict compliance with, and the mandatory nature of, the written protocol’s mandates.
839. Core Element # 5 of the Execution Protocol requires that “only the Director” of DRC can authorize a variation from the written execution protocol’s mandates.

840. But since the DRC Defendants' adoption of the execution protocol effective April 28, 2014 ("the 2014 Execution Protocol"), and continuing through the present, the Execution Protocol has allowed an indeterminate set of persons with undetermined qualifications or experience to authorize deviations/variations from the written protocol, because it defines "the Director" as "the Director" or *anyone the Director designates.*
841. The Execution Protocol defines "Director," as follows: "As used in the policy the term 'Director' refers to the current Director of the Ohio Department of Rehabilitation and Correction or *the Director's designee.*" (ECF No. 521, Execution Protocol, Section IV, p. 2 (PageID# 14161) (emphasis added).)
842. The term "Warden" is also redefined in the Execution Protocol to include not only the SOCF Warden or his Deputy Warden, but also "*the Director's designee.*" (*Id.*, Section IV, p. 3 (emphasis added).)
843. Accordingly, by the terms of the Execution Protocol, deviations from the written protocol may flow to any of an undefined number of persons, rather than to a single person as required under the previous written protocol.

844. Furthermore, nothing in the Execution Protocol provides how “the Director’s designees” will be identified, selected, designated, qualified, informed of such designation, or anything else; the protocol is silent other than to extend the Director’s execution-matter authority to an unknown set of persons without restrictions.
845. Similarly, the Wardens at SOCF, CCI, OSP, and TolCI are delegated numerous critical tasks throughout the Execution Protocol, but “the Warden” does not mean just the Wardens at SOCF or CCI or OSP or TolCI, but it also means *anyone the Director designates*.
846. Thus, during all times since the 2014 Execution Protocol, the Execution Protocol has exposed the illusory nature of the Core Elements on which the DRC Defendants have in the past defended their execution protocol against constitutional challenge, by redefining the terms “Director” and “Warden” to include anyone the Director (or the Warden) chooses to designate for a particular task or function, and without any minimal requirements on the qualifications, training, or competence of the “Director’s designee” or the “Warden’s designee.”
847. This redefinition of key terms in such a material respect starting with the 2014 Execution Protocol has effectively caused a substantial diminution if not outright elimination of Core Element # 5 in the Execution Protocol, even while the DRC Defendants seek to maintain the pretense that all core protections still exist in the Execution Protocol.

848. It used to be that the term “Director,” as used in the written execution protocol, meant just that, *i.e.*, the Defendant Director of DRC, in this case Defendant Gary Mohr. It likewise used to be that the term “Warden,” as used in the written execution protocol, meant just that, *i.e.*, the Defendant Warden of SOCF.
849. Thus, when written execution protocols that preceded the 2014 Execution Protocol included as key provisions that the “Director” or the Warden” would be responsible for a certain task or function as set forth in the written execution protocol, including the Core Elements, there was no ambiguity as to who was responsible or where the accountability lay. The buck stopped with the Director, and that meant the Director himself.
850. Only the person of the Director himself was allowed to authorize a variation from the procedures stated in the written execution policy, although allegedly not even the Director could authorize a deviation or variation from any of the four Core Elements enumerated in such written execution protocols that preceded the 2014 Execution Protocol.
851. But those protections and assurances were eliminated as a result of the DRC Defendants’ definitional changes starting with the 2014 Execution Protocol and continuing in the Execution Protocol.

852. The Execution Protocol now unambiguously allows the “Director” and the “Warden,” as those terms are everywhere used in the Execution Protocol, to be one and the same person, “the Director’s designee,” and that person might be neither the actual Director nor the actual Warden.
853. Or alternatively, these changes mean any of a wide variety of persons could function as “the Director” or “the Warden” at any given moment and at any given point during Defendants’ administration of the Execution Protocol to a given inmate.
854. “The Director” for purposes of authorizing one particular deviation from the written protocol might be different than “the Director” for purposes of authorizing a different deviation minutes, hours, days, or weeks later.
855. Nowhere does the Execution Protocol impose any restrictions whatsoever on the delegation of functions to the “Director’s designee.” The delegation is not regulated or constrained in any way at all in the Execution Protocol.
856. Nothing in the Execution Protocol provides how the Director’s designee will be identified, selected, designated, qualified, informed of such designation, or anything else; the protocol is silent other than to extend the Director’s execution-matter authority to an unknown set of persons without restrictions of any kind.

857. The policy allows for any and all of the “Director’s” and/or “Warden’s” duties and responsibilities in the execution process, whether specified in the Execution Protocol or not, to be delegated to some unidentified designee or designees at any time, in any context, and for any reason. Delegation may thus occur in some executions, but not others; it may pertain to only some functions or it may pertain to every single function; all as the Defendant Director, or any successor Director, may in the exercise of unbridled discretion choose to allow for a particular execution.
858. Not only are there no restrictions on the functions that can be delegated, but there are no restrictions or requirements on the competence, training, judgment, skill, or qualifications of who may be tabbed to be the “Director’s designee.” No minimal requirements have been established. There is no assurance that a “designee” has any knowledge of the execution process, much less that he/she is willing and/or able to enforce compliance with, and will not vary from, the Core Elements of the written execution protocol. There is, in short, no accountability required by the Execution Protocol.
859. A particular plaintiff being executed will have no clue as to which pattern of delegation, if any, will be used in *his* execution, because that is all a matter left to the arbitrary discretion of the Director or his designee.

860. By this newly adopted allowance of unbridled and unrestrained delegation, the DRC Defendants have further guaranteed that similarly situated plaintiffs will not be treated the same, as some will have untrained, unaccountable, and/or unknown “Director’s designees” making the key decisions in their execution, despite the facial assurances of the Execution Protocol, whereas others will have the Director himself.
861. The hierarchical oversight structure which the DRC Defendants previously presented to this Court, which terminated at the top in a single individual to whom all responsibility, communications, and potential deviations from the written protocol ultimately flowed up, and from whom every single authorization required by the Core Elements flowed down, is now merely illusory, making all elements of the Execution Protocol more akin to guidelines than mandatory requirements from which deviation will not be allowed absent authorization by a single person.

862. The use of untrained, unaccountable, and/or unknown “designees” in the execution process, and to perform the important duties of the Director and/or Warden, is itself a violation of one or more Core Elements of the Execution Protocol because, among other reasons, there is no assurance that such designees are willing and/or able to enforce the performance of an execution in a professional, humane, sensitive, and dignified manner and in accordance with, and without variance from, the Core Elements, and there is also no assurance that such designees will do so with the judgment, skill, and experience required for such a solemn task.
863. And, even if not itself a violation of Core Elements of the Execution Protocol, the use of untrained, unaccountable, and/or unknown “designees” in the execution process, and to perform the important duties of the Director and/or Warden, is so offensive to the spirit, purpose, and intent of the Core Elements of the Execution Protocol that such use must be deemed a violation of such Core Elements.
864. Defendants’ execution policy and Execution Protocol now make equal treatment of similarly situated individuals dependent upon the subjective interpretation and application of the Execution Protocol by any undefined person at any time and at any point in administration of the Execution Protocol, for any reason.

865. Similarly, equal treatment of similarly situated individuals is dependent upon the subjective interpretation and application of the Execution Protocol by any particular Director of DRC, which can and will change from Director to Director, and from “Director’s designee” to “Director’s designee,” without restrictions, all from execution to execution.
866. To the extent the Defendant Mohr has previously expressed his intention that he would only delegate Defendant Voorhies to act as the Director’s designee for any purposes under the Execution Protocol, that intention has not been included or otherwise memorialized in the Execution Protocol.
867. Additionally, the stated intentions of one Director, on such an important issue, are not sufficient to alleviate the deficiencies in the Execution Protocol, as identified in the preceding paragraphs, concerning the discretion conferred under the Execution Protocol for the Director to delegate all relevant duties and responsibilities to a Director’s designee; DRC Defendants abide by previously stated sworn testimony until they decide not to.

L. Additional allegations related to the contents of Defendants’ Execution Protocol.

868. The safeguards contained in Defendants’ written Execution Protocol are critical to avoid violating Plaintiff’s fundamental and constitutional rights in the course of an execution attempt.

869. The Execution Protocol, by its own terms, must be applied “in accordance with all applicable policies, administrative regulations, and statutes.” 2106 Execution Protocol, Sec. III at pp. 1 (ECF No. 667-1, Page ID 19812).
870. Upon information and belief, Defendants will employ an overarching execution policy that encompasses their informal execution policies, as well as the written execution protocol designated DRC Policy 01-COM-11 that is operable at the time, to execute Plaintiff.
871. Defendants’ overarching execution policy includes admissions and representations the DRC Defendants or their predecessors have made in response to discovery requests propounded during the course of the instant litigation.
872. Defendants’ overarching execution policy also includes representations that the DRC Defendants have made in various pleadings, motions and proceedings throughout the course of the instant litigation, including testimony presented in hearings before the Court.
873. Because the Execution Protocol must be applied in accordance with all applicable policies, administrative regulations, and statutes, the Core Elements of the Execution Protocol and their requirements must be construed subject to all applicable policies, administrative regulations, and statutes that have at least some element of overlap with those Core Elements.

874. Similarly, the Core Elements and their requirements must be construed subject to all applicable policies, administrative regulations, and statutes that have been incorporated explicitly in the Execution Protocol or implicitly through any unwritten policy or practice.
875. Deviation from overlapping applicable policies, administrative regulations, and statutes constitutes a deviation from relevant Core Elements.
876. Deviation from applicable policies, administrative regulations, and statutes that have been incorporated explicitly in the Execution Protocol or implicitly through any unwritten policy or practice constitutes a deviation from relevant Core Elements.
877. When there is substantial overlap and correlation between a Core Element and federal and Ohio state statutes and regulations, those federal and Ohio state statutes and regulations are implicitly incorporated into the Execution Protocol such that violation of the federal or state law constitutes a deviation from the relevant Core Element. *In re: Ohio Execution Protocol Litig. (Phillips)*, No. 2:11-cv-1016, 2013 WL 5963150, 2013 U.S. Dist. LEXIS 159680, *82–84 (S.D. Ohio Nov. 7, 2013). And if that deviation is not authorized in advance in writing by the Director, then that constitutes a deviation from Core Element # 5.

878. When Defendants have made concessions or representations that amount to unwritten or informal policies or practices incorporated into the Execution Protocol, then violation of those unwritten or informal policies or practices constitutes deviation from the relevant portion of the Execution Protocol. And if that deviation is not authorized in advance in writing by the Director, then that constitutes a deviation from Core Element # 5.
879. DRC Defendants have incorporated into the Execution Protocol (which is an administrative rule or regulation), as a matter of law, the Ohio state statutes and their associated regulations including, but not limited to, those related to controlled substances, manufactured drugs, imported drugs, compounded drugs, adulterated or misbranded drugs, prescribing requirements, and the practice of pharmacy. *See Cent. Ohio Joint Vocational School Dist. Bd. of Edn. v. Ohio Bur. of Emp. Servs.*, 487 N.E.2d 288, 292 (Ohio 1986) (“[A] a rule is invalid where it clearly is in conflict with any statutory provision.”); *In re Wedgewood Health Care Realty, L.L.C.*, 892 N.E.2d 960, 967 (Ohio App. 2008) (“Where an administrative rule conflicts with a legislative pronouncement, the administrative rule is invalid.”); *Hoffman v. State Med. Bd. of Ohio*, 865 N.E.2d 1259, 1262 (Ohio 2007) (citation omitted) (“[A]n administrative rule may not add to or subtract from a legislative enactment . . . If it does, it creates a clear conflict with the statute, and the rule is invalid.”); *Sanford v. D & T Limousine*

Serv., Inc., 671 N.E.2d 299, 304 (Ohio App. 1996) (“Any conflict, therefore, between a statute and administrative rule must be resolved in favor of the statute since administrative agencies are creatures of statute.”); *State v. Vannest*, No. 94 CA 1645, 1995 WL 761453, at *4 (Ohio App. 4th Dist. Dec. 15, 1995) (“Administrative agencies possess rule-making powers pursuant to a statutory delegation of power, and an administrative rule that is issued pursuant to statutory authority generally has the force of law. If, however, the administrative rule conflicts with a statute concerning the same subject matter, the statute takes precedence over the rule.”).

880. DRC Defendants have incorporated into the Execution Protocol, explicitly or implicitly through their unwritten policies or practices, the Ohio state statutes and regulations including, but not limited to, those related to controlled substances, manufactured drugs, imported drugs, compounded drugs, adulterated or misbranded drugs, prescribing requirements, and the practice of pharmacy.
881. DRC Defendants have incorporated into the Execution Protocol, as a matter of law under the federal Constitution’s Supremacy Clause, federal statutes and regulations including, but not limited to, those related to controlled substances, manufactured drugs, imported drugs, compounded drugs, adulterated or misbranded drugs, and prescribing requirements.

882. DRC Defendants have made concessions or representations that amount to unwritten or informal policies or practices incorporated into the Execution Protocol.
883. One or more of the DRC Defendants have testified under oath that they consider the written execution protocol to be more akin to discretionary “guidelines” rather than binding, mandatory law, and that they believe the execution policy and written execution protocol gives Defendants discretion to deviate/vary from the policy and protocol’s mandates to carry out an execution.
884. On or about August 17, 2010, including in a sworn affidavit signed by the Director of DRC on or about August 20, 2010, the DRC Defendants made several commitments which they represented are part of their “informal” execution policy. (*See Cooey*, ECF No. 817; *see also Cooey*, ECF No. 817-1, PageID 17564–65.) Several of these commitments were sworn and filed on the record of this case.
885. Among Defendants’ informal execution policies are the following:
- a) Defendants will not commence any execution unless they have, on hand in the Death House at SOCF, at least 10 grams—*i.e.*, a full 5-gram dose and a full 5-gram back-up dose—of the lethal execution drug.
 - b) If Defendants do not have 10 grams of the barbiturate for the single-drug execution method on hand in the Death House, Defendants will not commence an execution.
 - c) Defendants will not transfer an inmate scheduled for execution to SOCF unless Defendants have 10 grams of the intravenously injected execution drug at SOCF.
 - d) Defendants will not use imported execution drugs.

- e) Defendants will not use any execution drug that is expired at the time of the scheduled execution, according to the expiration date stamped on the original manufacturer's packaging.
 - f) Defendants will use only execution drugs that are pure, unadulterated, unexpired, not compounded, and in the sealed, original manufacturer's packaging.
886. These informal policies contemplated thiopental sodium as the drug to be administered via IV injection, which Defendants used in the execution of Frank Spisak on February 17, 2011.
887. Defendants' policies that explicitly apply to thiopental sodium remain binding as to Defendants' inclusion of thiopental sodium in the 2016 Execution Protocol.
888. The concerns that underpinned Defendants' informal policies as to thiopental sodium apply with equal weight to the use of pentobarbital, midazolam, a paralytic drug, potassium chloride, or any other execution drug(s) Defendants may contemplate.
889. DRC Defendants previously testified under oath and assured this Court that they would not use compounded execution drugs.
890. DRC Defendants have testified under oath and assured this Court that they would not use imported execution drugs.
891. DRC Defendants have previously testified under oath and assured this Court that they would not use expired execution drugs, and that they would not use expired execution drugs that have been given an extended expiration date.

892. The Director of DRC has testified under oath that Defendants would not use expired or imported execution drugs for an execution, and this Court has held that Defendants are bound by that testimony.
893. Using expired execution drugs or drugs that are past their use-by date or which have been given an extended expiration date creates a substantial risk of serious harm to Plaintiff, because it is sure or very likely that such drugs are contaminated, adulterated, not of the correct identity, super- or sub-potent, or in myriad other ways not identical to non-expired execution drugs. And that, in turn, makes it sure or very likely that Plaintiff will be subjected to severe harm, including serious physical and/or mental or psychological pain and suffering, a lingering death, a spectacle execution that is not dignified, and other risks that are objectively intolerable but which Defendants ignore.
894. There is substantial overlap and correlation between Core Element # 2, which establishes that “the drugs required by this policy shall be used,” and the federal and Ohio state statutes and regulations related to controlled substances, manufactured drugs, imported drugs, compounded drugs, adulterated or misbranded drugs, prescribing requirements, and the practice of pharmacy, medicine and/or nursing, as those federal and state statutes and regulations tightly regulate, and/or control access to, the very drugs Defendants intend to use in the Execution Protocol, such that those federal and state

administrative regulations and statutes are implicitly incorporated into Core Element # 2.

895. There is substantial overlap and correlation between Core Element # 1 which establishes that “three Medical Team Members, two of whom are authorized to administer drugs under Ohio law, shall be used in the conduct of court-ordered executions,” and the federal and Ohio state statutes and regulations related to controlled substances, manufactured drugs, imported drugs, compounded drugs, adulterated or misbranded drugs, prescribing requirements, and the practice of pharmacy, as those federal and state statutes and regulations tightly regulate, and/or control access to, and the authorization to administer, the very drugs Defendants intend to use in the Execution Protocol, such that those federal and state administrative regulations and statutes are implicitly incorporated into Core Element # 1.

896. There is substantial overlap and correlation between Core Element # 3, which establishes that “[f]unctions required to be performed by medically-qualified persons, as described in this policy, shall be performed by Medical Team Members,” and the federal and Ohio state statutes and regulations related to controlled substances, manufactured drugs, imported drugs, compounded drugs, adulterated or misbranded drugs, prescribing requirements, and the practice of pharmacy, medicine and/or nursing, as those federal and

state statutes and regulations tightly regulate, and/or control access to, the very drugs Defendants intend to use in the Execution Protocol, and thus who can be considered “medically qualified” under those laws and as to which functions, such that those federal and state administrative regulations and statutes are implicitly incorporated into Core Element # 3.

897. On or about September 18, 2015, Defendants represented to the Court that Defendants have not, and will not, illegally obtain execution drugs, thereby implicitly incorporating into the Execution Protocol, by concession or representation that amounts to an unwritten or informal policy or practice, all federal and state administrative regulations and statutes related to controlled substances, manufactured drugs, imported drugs, compounded drugs, adulterated or misbranded drugs, prescribing requirements, and the practice of pharmacy, medicine, and/or nursing, as those federal and state statutes and regulations tightly regulate, and/or control access to, the very drugs Defendants intend to use in the Execution Protocol.
898. On or about September 18, 2015, Defendants represented to the Court that Defendants have not, and will not, illegally obtain execution drugs, thereby implicitly incorporating into the Execution Protocol, by concession or representation that amounts to an unwritten or informal policy or practice, all federal and state

administrative regulations and statutes that are overlapping with the Execution Protocol by virtue of regulating or otherwise controlling matters related to controlled substances, manufactured drugs, imported drugs, compounded drugs, adulterated or misbranded drugs, prescribing requirements, and the practice of pharmacy, medicine, and/or nursing, as those federal and state statutes and regulations tightly regulate, and/or control access to, the very drugs Defendants intend to use in the Execution Protocol.

899. Also among Defendants' informal execution policies that are implicitly incorporated into the Execution Protocol are the following provisions concerning Defendants' possession of a sufficient quantity of the intravenously injected execution drug. Notably, these provisions are related, but they are discrete provisions with different requirements:
- g) A "notice" provision stating that DRC Defendants "will provide notice to a condemned inmate's counsel and Plaintiffs' counsel (if different) within a reasonable time period (no less than 5 days) before an execution if [DRC] does not have in its possession at least 10 grams of thiopental sodium at that time," (*Cooey*, ECF No. 817-1, PageID 17564–65); and
 - h) A "reprieve" provision stating that "[c]oncurrent with such notice to counsel, [DRC Defendants] will also immediately seek a reprieve from the Governor related to that condemned inmate's execution," (*id.* at PageID 17565).

900. Also among Defendants' informal execution policies implicitly incorporated into the Execution Protocol are the following provisions related to any intent or action by DRC Defendants to change their written execution protocol. Notably, these provisions are related, but they are discrete provisions with different requirements:

- i) A "notice" provision stating that DRC Defendants "will provide notice to the Court, to a condemned inmate's counsel and to Plaintiffs' counsel (if different) within a reasonable time period (no less than 30 days) before an execution if [DRC] intends to change the written execution policy, ODRC Policy 01-COM-11," (*Cooey*, ECF No. 817-1, PageID 17565), and;
- j) A "reprieve" provision stating that "[c]oncurrent with such notice to counsel, [DRC Defendants] will seek a reprieve from the Governor related to that condemned inmate's execution, *provided that* the execution is scheduled to take place less than thirty days *from the effective date* of the change in policy," (*id.* (emphases added)).

901. Also among Defendants' information execution policies implicitly incorporated into the Execution Protocol are the November, 2009 sworn representations to this Court, the Sixth Circuit, the public and Plaintiffs that Defendants would no longer use a paralytic drug or potassium chloride as part of a lethal injection execution method.

902. On or about March, 2012, DRC Defendants testified that they had implemented Incident Command Systems as part of the execution policy. Accordingly, the processes, procedures and other requirements of ICS are implicitly incorporated into Defendants' Execution Protocol.

903. The 2016 Execution Protocol allows “the Medical Team” the unfettered, unguided discretion to determine, at any time, which execution method will be used for any given inmate, by granting “the Medical Team” the unfettered, unguided discretion to determine, at any time, whether “available” execution drugs are “unusable.”
904. The Execution Protocol does not contain any substantive or procedural provisions by which execution drugs will be deemed “available,” or “useable.”
905. The Execution Protocol contains no substantive or procedural provisions by which “the Medical Team” will reach its decisions, such as how many Medical Team members must make the decision, whether the decision must be unanimous or something else, whether any such decision may be unilateral by a single member of the Medical Team, or anything else.
906. The Execution Protocol does not actually require that Defendants notify the condemned inmate of how he or she will be executed, since that determination can be made “at any time” by some unknown number of the Medical Team using an unknown, undefined decisional process.
907. Defendants fail to conduct the evaluations required under the Execution Protocol sufficiently to ensure against the substantial risk of harm created by the intravenous administration of any of the drugs in the Execution Protocol.

908. Defendants represented to this Court that they have not, and will not, illegally obtain execution drugs, but Defendants' purported adherence to that informal policy is undermined by, for example, recent evidence that Defendants took concrete steps to obtain imported execution drugs that Defendants knew or should have known are illegal to import.
909. Defendants have demonstrated that they will alter their positions as related to execution drugs as Defendants deem necessary to carry out an execution.
910. In light of Defendants' history of changing their positions on execution drugs that may be used for an execution, along with their previous refusal or failure to destroy or otherwise divest themselves of the expired execution drugs in their possession, and their simultaneous insistence that they will not and have not illegally obtained execution drugs when the available evidence suggests intentions otherwise, there is a substantial risk that Defendants, finding it difficult or impossible to carry out an execution using only non-imported, legally obtained and legally dispensed, distributed and administered execution drugs that are not expired and not past their use-by date, will resort to using drugs that are illegally obtained, dispensed, distributed or administered or expired or past their use-by date, despite previous sworn testimony and assurances to this Court.

911. The changes to Defendants' execution protocol from the time that lethal-injection was first adopted as an execution method in Ohio increase the risks of harm associated with the protocol and Defendants' application of the execution protocol to Plaintiff.
912. Recent revisions to the Ohio Revised Code, § 2949.221–222, that were specifically sought by Defendants and signed into law by Defendant Kasich significantly reduce, if not entirely eliminate, the procedural protections the Execution Protocol allegedly provides, by attempting to hide from disclosure (and thus any meaningful oversight) a wide variety of factual information related to Defendants and the administration of the Execution Protocol.
913. When information was previously uncovered about DRC Defendants and their actions related to executions, troubling constitutional violations were revealed. Defendants claim to strictly adhere to the Execution Protocol and to follow the law in carrying out executions, but only through meaningful independent oversight can that claim be assessed. By drawing a cloak of secrecy over virtually everything related to executions, Defendants substantially increase the significant and demonstrated risk of unconstitutional and illegal activity in which Defendants engage related to executions.

M. Defendants deviate or vary from the mandates of their written Execution Protocol, consistently fail to follow their informal execution policies, and falsify official documents and records.

914. Defendants' actions involving execution drugs to be used under the Execution Protocol are "institutional policy" and "systemic practices" applicable to all Defendants; they are not merely individualized misconduct of poor employees or agents that cannot be fairly attributable to Defendants. *See In re: Ohio Execution Protocol Litig. (Phillips)*, No. 2:11-cv-1016, 2013 WL 5963150, 2013 U.S. Dist. LEXIS 159680, *82-84 (S.D. Ohio Nov. 7, 2013).
915. Accordingly, a violation of federal or Ohio state statutes and regulations, by or under the direction of any of the Defendants, related to Defendants' actions regarding execution drugs is a violation of Core Element # 2 that is attributable to all Defendants.
916. DRC Defendants deviate from Core Element # 2 by injecting the inmate with execution drugs that are not the dosage and/or concentration required to be used by the Execution Protocol.
917. For instance, upon information and belief, Defendants injected Dennis McGuire with drugs in dosages and concentrations that were not the precise dosages and concentrations required by 01-COM-11. Thus, Defendants deviated from Core Element # 2 in the McGuire execution.
918. Injecting McGuire with drugs other than the required dosage and concentration was also a deviation from Core Element # 5 because no

such deviation was authorized in advance in writing by the Incident Commander.

919. Upon information and belief, Defendants injected Ronald Phillips with drugs in dosages that were not the precise dosages required by 01-COM-11. Thus, Defendants deviated from Core Element # 2 in the Phillips execution.

920. Injecting Phillips with drugs other than the required dosage was also a deviation from Core Element # 5 because no such deviation was authorized in advance in writing by the Incident Commander.

921. Upon information and belief, Defendants injected Gary Otte with drugs in dosages that were not the precise dosages required by 01-COM-11. Thus, Defendants deviated from Core Element # 2 in the Otte execution.

922. Injecting Otte with drugs other than the required dosage was also a deviation from Core Element # 5 because no such deviation was authorized in advance in writing by the Incident Commander.

923. Defendants will not inject Plaintiff with drugs in the dosages that are not the precise dosages required by 01-COM-11.

924. Defendants deviate from Core Element # 2 by using any of the drugs in the Execution Protocol as an execution drug, because there is no pending IND Application to use thiopental sodium, pentobarbital, midazolam, the paralytic drug, or potassium chloride as an execution drug submitted to FDA by any Defendants, and thus using any of those drugs violates the federal prohibition on using unapproved new drugs without a pending Investigational New Drug Application.
925. Defendants deviate from Core Element # 2 by using imported execution drugs, because DRC Defendants have previously conceded as part of an unwritten or informal policy or practice incorporated into the Execution Protocol that they will not use imported execution drugs as part of their execution protocol.
926. Defendants deviate from Core Element # 2 by using imported thiopental sodium as an execution drug, because thiopental sodium is not a drug approved by the federal FDA and therefore it may not be legally imported into the United States.
927. Defendants deviate from Core Element # 2 by using imported pentobarbital as an execution drug to the extent that Defendants do not possess a valid registration with DEA to import pentobarbital.

928. Defendants deviate from Core Element # 2 by using imported execution drugs under the Execution Protocol, to the extent such execution drugs were manufactured overseas in a facility not registered with the FDA, because such drugs are considered “misbranded” and thus may not be legally imported into the United States.
929. Defendants deviate from Core Element # 2 by using imported execution drugs under the Execution Protocol, to the extent that the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current Good Manufacturing Practices; such finished drug product would be considered adulterated under federal law, and therefore may not permissibly be manufactured, sold, delivered, or held or offered for sale under federal law.
930. Defendants deviate from Core Element # 2 by using imported execution drugs under the Execution Protocol to the extent that the finished drug product’s strength differs from, or its quality or purity falls below, applicable standards established in the United States Pharmacopeia and the national formulary; such finished drug product would be considered adulterated under federal and Ohio state law, and therefore may not permissibly be manufactured, sold, delivered, or held or offered for sale under federal and Ohio state law.

931. Defendants deviate from Core Element # 2 by using compounded pentobarbital or compounded thiopental sodium or compounded midazolam as an execution drug, because none of those drugs may be permissibly compounded without a valid prescription, and obtaining a valid prescription for using controlled substances such as each of those three drugs in an execution is impossible under federal and Ohio law. A prerequisite for a prescription for a controlled substance to be valid under federal law is that the order must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. An order purporting to be a prescription that was not issued in the usual course of professional treatment or in legitimate and authorized research is not a valid prescription under federal law. And under Ohio law, a prescription, to be valid, must also be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of his/her professional practice. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a valid prescription under Ohio law.
932. Defendants deviate from Core Element # 2 by using adulterated thiopental sodium as an execution drug, because DRC Defendants have conceded as part of an unwritten or informal policy or practice incorporated into the Execution Protocol that they will not use adulterated thiopental sodium as part of their execution protocol.

933. Defendants deviate from Core Element # 2 by using compounded pentobarbital or compounded thiopental sodium or compounded midazolam as an execution drug to the extent that the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current Good Manufacturing Practices; such finished drug product would be considered adulterated under federal law, and therefore may not permissibly be manufactured, sold, delivered, or held or offered for sale under federal law.
934. Defendants deviate from Core Element # 2 by using compounded pentobarbital or compounded thiopental sodium or compounded midazolam as an execution drug to the extent that the finished drug product's strength differs from, or its quality or purity falls below, certain standards established in the United States Pharmacopeia and the national formulary; such finished drug product would be considered adulterated under federal and Ohio state law, and therefore may not permissibly be manufactured, sold, delivered, or held or offered for sale under federal and Ohio state law.
935. Defendants deviate from Core Element # 2 by using compounded pentobarbital or compounded thiopental sodium or compounded midazolam as an execution drug, because each of those compounded drug products would be considered dangerous to health or health-

endangering when used as “prescribed” to execute Plaintiff, and therefore characterized as “misbranded” under federal law and Ohio law, and therefore may not permissibly be manufactured, sold, delivered, or held or offered for sale under federal and Ohio state law.

936. Defendants deviate from Core Element # 2 by using compounded pentobarbital or compounded thiopental sodium or compounded midazolam as an execution drug if it is compounded by a so-called 503A Compounding Pharmacist; under federal and Ohio state law, a 503A Compounding Pharmacy may only compound or dispense a compounded product pursuant to a valid prescription order or a notation on a valid prescription order that a compounded product is necessary for the identified patient. Because a drug used to kill Plaintiff can never be said to be “necessary” for him under the law, a 503A Compounding Pharmacist would not have a legitimate prescription or notation from a prescribing practitioner of the necessity for a compounded drug, and thus could not prepare and dispense drugs to be used for a lethal-injection execution while remaining in compliance with federal and Ohio state law.

937. Defendants deviate from Core Element # 2 by using compounded pentobarbital or compounded midazolam as an execution drug if it is compounded by a so-called 503B Outsourcing Facility; a 503B Outsourcing Facility is prohibited from producing drug products that are “essentially a copy of an approved drug,” such as pentobarbital and midazolam.
938. Defendants deviate from Core Element # 2 by using expired execution drugs, including drugs that are past their “beyond-use” date, because DRC Defendants have conceded as part of an unwritten or informal policy or practice incorporated into the Execution Protocol that they will not use expired execution drugs as part of their Execution Protocol.
939. Defendants deviate from Core Element # 2 by using non-sterile, impure, contaminated, adulterated, misbranded or illegally obtained execution drugs because the Execution Protocol does not allow for use of non-sterile, impure, contaminated, adulterated, misbranded or illegally obtained execution drugs.
940. Defendants deviate from Core Element # 2 by using adulterated execution drugs because DRC Defendants have conceded that they will not use adulterated execution drugs.
941. Defendants deviate from Core Element # 2 by using rocuronium bromide for Plaintiff’s execution that was removed from refrigeration storage to room temperature storage more than 60 days before

Plaintiff's execution, because removing that drug to room temperature conditions makes the drug adulterated after 60 days.

942. Upon information and belief, Defendants will use a supply of rocuronium bromide for Plaintiff's execution that was removed from refrigeration storage to room temperature conditions during an execution that preceded Plaintiff's scheduled execution by 60 days or more.
943. Defendants deviate from Core Element # 2 by using compounded drugs that have not been compounded in full compliance with USP <797>, and therefore are compounded in violation of Ohio law, including the requirements for analytical testing of purity, sterility, the presence of pyrogens and other potential contaminants, and other prophylactic measures that make strict compliance with USP <797> so demanding.
944. Defendants deviate from Core Element # 2 by using execution drugs that are not the exact type of drug, in the quantities mandated in the written protocol and in the concentrations as those drugs are manufactured in the FDA-approved form, because the written protocol does not allow for use of any execution drugs other than the specific type of drug in the specific quantities and concentrations mandated in the Execution Protocol.
945. Defendants deviate from Core Element # 2 by using execution drugs with an improper pH and/or any other defining characteristic of the

drug found in the official U.S. Pharmacopeia Monograph for the drug, because DRC Defendants have conceded that “the applicable USP/NF monograph” is the appropriate standard for execution drugs used as part of the execution protocol.

946. Defendants deviate from Core Element # 2 by using the paralytic drug, because DRC Defendants represented in November 2009 to the public, and under oath to this Court, the Sixth Circuit, and the Plaintiffs, that they would no longer use the drug as part of their Execution Protocol.
947. Defendants deviate from Core Element # 2 by using potassium chloride, because DRC Defendants represented in November 2009 to the public, and under oath to this Court, the Sixth Circuit, and the Plaintiffs, that they would no longer use the drug as part of their Execution Protocol.
948. Defendants deviate from Core Element # 2 on every occasion when they carry out an execution that is experimental or that includes the use of experimental or unapproved drugs on an inmate, or otherwise engage in actions to administer the Execution Protocol that violate DRC policies such as 68-MED-11 and its associated protocols, 06-RES-01, or 06-RES-02, because those DRC policies are implicitly incorporated into the Execution Protocol.

949. For all of the reasons identified above by which Defendants deviate from Core Element # 2, they also deviate from Core Elements # 1 and # 3.
950. This is because Core Elements # 1 and # 3 require that Medical Team Members who administer the drugs to Plaintiff for his execution must “be authorized to administer drugs under Ohio law,” and, with respect to the “functions” such Medical Team Members are required to perform, they must be “medically-qualified persons.”
951. Any authorization any such Medical Team Members may possess to “administer drugs under Ohio law” includes, as a minimum requirement, express or implied, that their administration of such drugs not be in violation of Ohio law or federal law. None of the Medical Team Members does or can meet that requirement if and to the extent any of the deviations identified above with respect to Core Element # 2 exist for any particular execution. Each of the Medical Team Members exceeds, and therefore violates, his/her authorization to administer drugs under Ohio law in the circumstance of any execution in which any of the deviations identified above with respect to Core Element # 2 exist.
952. Similarly, any qualifications any of the Medical Team Members may possess to perform the medical functions they are required to perform in an execution under the Execution Protocol include, as a minimum qualification, express or implied, that their performance of their

medical functions complies with all governing and applicable laws and regulations, including the applicable ethics standards and applicable professional standards of practice. When the performance of a medical function under the Execution Protocol violates federal and/or Ohio law or applicable ethics or professional practice standards, there is no Medical Team Member who is “medically-qualified” to perform that function. The performance by a Medical Team Member of a medical function under the Execution Protocol, where the performance of that function is in violation of federal and/or Ohio law or applicable ethics or professional practice standards, is a medical function that no Medical Team Member is medically-qualified to perform. No Medical Team Member is medically-qualified to perform any medical function whose performance involves any of the deviations identified above with respect to Core Element # 2.

953. DRC Defendants deviate from Core Element # 5 on every occasion when they prematurely take actions under 01-COM-11 that are not supposed to occur until death has occurred, and when they fail to take actions required to be done until the prisoner is dead, and there is no record of the Director’s written authorization to engage in such deviations.

954. For example, it is substantially likely that Dennis McGuire was still clinically and statutorily alive when DRC Defendants took actions under 01-COM-11 to declare him dead, and when they took other actions that followed. DRC Defendants acted to close the curtain to the Death Chamber and to evaluate McGuire by the “appropriate medical professional” to “confirm death” before “the completion of the process.”
955. DRC Defendants likewise acted before “a sufficient time for death to have occurred” when they closed the curtain ten minutes after injection, and when they took subsequent actions as to Dennis McGuire.
956. Each of those actions was a deviation from 01-COM-11.
957. There is no evidence that the Director authorized any deviation during the McGuire execution in any way, and certainly no evidence that the Director authorized those deviations in writing.
958. Defendants deviated from Core Element # 5 when they prevented Attorney Wright from “hav[ing] free access to the phone near the entrance door of the Death House” during the execution of Gary Otte, and that deviation was not authorized in writing in advance by the Incident Commander.
959. DRC Defendants consistently and regularly deviate or vary from their execution policy and written protocol in numerous ways, big and small, such that DRC Defendants have a long-standing pattern of

deviations and/or variations from their execution policy and written execution protocol.

960. DRC Defendants' pattern of deviations and/or variations continues to this day. Ohio has a lengthy execution schedule. Each execution process presents yet another opportunity for Defendants to deviate from their Execution Protocol.
961. The record in this case is replete with evidence of Defendants deviating or varying from the mandates of their written Execution Protocol and from their information execution policies. *See, e.g., Cooey v. Kasich (Kenneth Smith)*, 801 F. Supp. 2d 623, 625–52 (S.D. Ohio 2011), factual findings contained therein alleged here by reference; *In re Ohio Execution Protocol Litigation (Charles Lorraine)*, 840 F. Supp. 2d 1044, 1055–59 (S.D. Ohio 2012) (same); Amended Omnibus Compl., ECF No. 158, ¶¶728–790, allegations incorporated here by reference.
962. This includes deviations from core requirements of the written Execution Protocol, as well as deviations which were core deviations because they were unauthorized deviations from non-core elements of the written Execution Protocol.
963. By these deviations and/or variations, Defendants ignore and/or recklessly disregard their execution policy's and written Execution Protocol's requirements.

964. Defendants' pattern of deviations and/or variations from their execution policy and written Execution Protocol means that Defendants will arbitrarily and irrationally administer their execution policy and written Execution Protocol differently each time they execute an inmate.
965. There are no legitimate governmental or penological reasons for these deviations and/or variations.
966. Defendants' deviations and/or variations are not necessary to achieve a compelling governmental interest.
967. DRC Defendants rely on ICS to immunize their execution method from constitutional challenge.
968. But DRC Defendants do not strictly comply with the tasks and requirements established by their use of ICS as part of the execution policy.
969. The veracity of the documents and records DRC Defendants create that purport to demonstrate strict compliance with the written Execution Protocol and informal execution policies is undermined by evidence of falsification of official records and documents, and by official records and documents that do not accurately reflect the proceedings that occurred or that seek to sanitize such proceedings.

970. This includes the falsification and/or sanitization and/or incomplete character of official records and documents related to significant events involving inmates in DRC Defendants' control and subject to DRC Defendants' procedures.
971. DRC Defendants or their agents falsified official records and documents following the suicide of former Plaintiff Billy Slagle during the "First Operational Period" of DRC Defendants' administration of 01-COM-11 to Slagle.
972. Following Slagle's suicide, DRC Defendants claimed to have previously had in place a policy to facilitate attorney-client communication and access at all times, when no such policy existed at that time.
973. The official After-Action Review and other related documentation produced in accordance with DRC Defendants' alleged implementation of ICS for administering 01-COM-11 to Slagle contains falsehoods and misrepresentations.
974. Upon information and belief, the evidence of actions DRC Defendants took related to Slagle's suicide does not comport with the actions required under the relevant ICS documentation.
975. Official records and documents were falsified following the suicide of inmate Ariel Castro while in custody and control of DRC.
976. Spurious allegations about Castro—which might have placed the DRC Defendants and their agents in a better light—were included in an official report that had no basis in fact.

977. Investigators conducting the “investigation” into matters related to the execution of Dennis McGuire were not independent investigators at all, but rather two attorneys from the same division of the Ohio Attorney General’s Office that represents DRC Defendants in this litigation.
978. Yet the public impression DRC Defendants purposely conveyed was that the investigation was an independent investigation.
979. The investigators entire “investigation” regarding the McGuire execution consisted of interviewing DRC employees (who, by the virtue of their employment as Defendants in this litigation and/or as DRC employees had a vested interest in minimizing the official account of what happened during that execution) and asking leading questions about what those employees witnessed.
980. Upon information and belief, the “investigators” interviewed no independent witnesses of the McGuire execution as part of the “investigation,” nor did “investigators” interview any of the witnesses present on behalf of McGuire.
981. Nevertheless, the April 28, 2014 After-Action Review and Executive Summary related to the execution of McGuire strongly and repeatedly implies that investigators interviewed witnesses other than DRC employees.
982. The same report significantly downplays the description of what occurred in the Death Chamber during the execution of McGuire.

983. The same report implies that DRC Defendants and/or their counsel and/or the “investigators” from the Attorney General’s Office corresponded and consulted with Dr. Dershwitz to reach their findings and recommendations. But that is not true.
984. DRC Defendants and/or their agents wrongly and misleadingly suggested that Dr. David Waisel “recommended” an execution method, and that DRC Defendants adopted their 2014 Execution Protocol based on that purported “recommendation,” but Dr. Waisel emphatically did NOT in any way offer any recommendation, endorsement, suggestion, or anything else as to Defendants’ new execution protocol.
985. The Execution Timeline log that purportedly contains all significant events that took place during McGuire’s execution lacks any entry describing the horrific spectacle that unfolded in the Death Chamber following injection of the execution drugs.
986. The ICS documents created related to the McGuire execution falsely give the impression that there was nothing out of the ordinary that occurred during that execution.
987. The “After-Action” documentation related to the execution of Gary Otte paints the picture of an execution that went off without an complications and with full compliance with 01-COM-11.
988. But that is false. Defendants’ own physical assessment of Otte approximately 30 days before execution noted that Otte was “morbidly

obese.” That fact alone should have alerted Defendants that Otte was likely to obstruct during his execution, like what was observed with McGuire.

989. Thus, the very real likelihood that Otte would obstruct and suffer air hunger was at least a “potential problem” that Defendants were required to note and discuss, along with potential solutions considered, “in advance of the execution.” Defendants failed to note or discuss the sure or very likely risk that Otte would obstruct and suffer air hunger during his execution, which is also a deviation from Core Element # 5.
990. Likewise, Defendants were required to communicate the concerns or potential issues regarding Otte’s morbid obesity and resulting likelihood of obstructing during his execution to the Warden or designee at SOCF. No concerns or potential issues were communicated to the SOCF Warden or his designee in advance of the Otte execution, which is also a deviation from Core Element # 5.
991. 01-COM-11, ¶ VI.G.8.c, requires Defendants to “announce the number of attempts made to establish viable IV site(s) to the Command Center contact who shall then inform the Command Center, for capture on the Execution Timeline.”
992. 01-COM-11, ¶ VI.G.8.d, requires the “Command Center shall record in the Execution Timeline the number of [IV insertion] attempts.”

993. During Otte's execution, Execution Team members made at least two IV insertion attempts on Otte's right arm.
994. TM # 21, however, announced there was only one attempt in each arm, and the Execution Timeline recorded that there was one attempt in each arm.
995. By announcing incorrect information, and by recording incorrect information for a matter that is subject to mandatory recording on the Execution Timeline, Defendants deviated from the execution protocol. Those deviations were not authorized in advance, in writing, by the Incident Commander, which constitutes two deviations from Core Element # 5.
996. Defendants have also provided false assertions to the Court on related matters.
997. Defendants represented their full compliance with this Court's evidence preservation order, but later conceded that was inaccurate.
998. This Court ordered Defendants to preserve certain evidence from the Phillips execution, including a requirement to photograph the drug vials, the boxes for those vials, and other materials. (ECF Nos. 1107 and 1115).
999. Paperwork completed and signed by Defendant Erdos, Warden of SOCF, at 11:15 a.m., just 30 minutes after Phillips was declared dead at 10:43 a.m., explicitly recorded compliance, indicating that "all vials, syringes, medication boxes and intravenous tubing has been

preserved,” and that the “evidence was taken to the pharmacy along with the unused and/or unprepared drugs by the drug administrator.” (Phillips Execution Evidence Preservation Memo, 08/18/2017 Discovery, Bates 002810).

1000. Counsel for Defendants then filed a “Notice of Compliance with Order to Preserve Execution Materials” on August 1, 2017, several days after the Phillips execution (ECF No. 1133) which also indicated that the materials had been preserved.
1001. The next day, however, Defendants conceded in a “Corrected Notice” that some of those materials were, in fact, destroyed after the execution, contrary to their previous representation to this Court and Plaintiffs. (ECF No. 1137.)
1002. Defendants were also commanded to “preserve without alteration the medication vials, the boxes in which they were packaged, the intravenous tubing, and the syringes used in the administration of the protocol drugs at the Phillips execution.” (ECF No. 1107, PageID 42815.)
1003. But Defendants did alter those vials.
1004. DRC “Execution Drug Disposal and/or Return” Form indicates that Defendants discarded the contents of the backup syringes after the execution was complete (Execution Drug Disposal and/or Return, 08/11/2017 Discovery, Bates 002615), in contravention of this Court’s instructions.

1005. Defendants' spoliation of evidence and their false representations to this Court further call into question the representations and documentation that Defendants offer to claim they strictly comply with the execution protocol.

N. Allegations related to Plaintiff's individual characteristics.

1006. Allegations related to Plaintiff's individual characteristics will be alleged in the Plaintiffs' Amended Individual Supplemental Complaints to be filed in this case in accordance with the court's scheduling order.

O. Allegations involving examples of specific, relevant executions or execution attempts.

Unidentified execution in or about 2004

1007. Former SOCF Warden James Haviland has testified in this case about an execution in which he participated when the three-drug method was used but problems developed.

1008. Haviland was standing next to the inmate (whose name he did not recall), as was his job as the warden at that time. Team Member # 18 was administering the drugs from the "equipment room," a distance of approximately 10–15 feet from the inmate. Haviland saw the inmate's arm above the IV site start to "balloon up," but he did not know what that meant nor did he do anything about it until after the execution when he raised the issue with Team Member # 18.

1009. Team Member # 18 told Haviland that he had felt pressure during the administration of the drugs so he decided to switch lines midstream. (Haviland Depo at 59-65, 78, 210; TM#18 Depo at 302-15.)
1010. That meant that some or all of the drugs administered in that first line never reached the inmate's circulatory system, and, thus, did not induce the level of anesthesia required. As a result, when the rest of the drugs were "pushed" by TM #18 into the second line, the inmate experienced the painful drugs without sufficient, or possibly any, protection from the pain.
1011. The fact that the inmate did not express pain was not because he did not feel pain, but, instead, because he was paralyzed and was unable to effectively communicate his internal distress.

Wilford Berry

1012. DRC Defendants executed Wilford Berry on February 19, 1999 using a three-drug method.
1013. Despite applying Incident Command Systems principles as a part of their execution policy at the time, Defendants failed to strictly adhere to execution policy and the written execution protocol during the execution.
1014. Upon information and belief, the members of Berry's execution team could not locate a vein for the IV line, so they resorted to violently beating his arms in order to raise a vein adequate to acquire an IV site for the transmission of the lethal drugs into his body.

Joseph Clark

1015. DRC Defendants executed Clark on May 2, 2006 using a three-drug method.
1016. During the execution, Defendants failed to administer the required, and critical, full dose of two grams of sodium thiopental via peripheral IV injection before injecting the paralytic drug and potassium chloride.
1017. Execution team members were only able to establish and maintain one IV line. Despite the protocol's requirement to establish two working IV sites, Defendants decided to start the execution anyway.
1018. Some amount of time after the drugs started flowing into the IV tubing, Clark raised his head and upper body off the table several times and said, "It don't work. It don't work." According to media witnesses, Clark repeated this statement five times during his execution.
1019. The media who were present also reported that "[m]edical technicians returned and the curtain was closed at 10:37 a.m., blocking the view of authorized witnesses, who later heard what they described as 'moaning, crying out and guttural noises.'" Alan Johnson, '*It don't work,' inmate says during botched execution*, COLUMBUS DISPATCH (May 3, 2006).

1020. It took more than 90 minutes for a new viable IV site to be established. During that time, Clark moaned and suffered. He was poked and stuck with needles at least 17 or 18 times, including in his neck and head.
1021. DRC Defendants eventually established an IV in one of Clark's arms only after one of the non-medical (security) team members, a former semi-pro football player, used his bare hands to squeeze Clark's arm so tightly that a vein popped out in Clark's right forearm. An execution team member "stuck" that vein, and that site was then used as the sole site for the continued execution.
1022. The Execution Team was prepared to go until midnight if necessary, poking and sticking Clark, as former DRC Director Collins acknowledged.
1023. The Drug Administrator for the Clark execution saw no problem with the course of action DRC Defendants took during the Clark execution.
1024. The written protocol in effect at that time required peripheral IV injection of two grams of sodium thiopental, divided into two syringes, to ensure the inmate was properly made "unconscious" before administration of the second (pancuronium bromide) and third (potassium chloride) drugs.
1025. But DRC Defendants had dispensed the Clark execution drugs from the DRC pharmacy to an unknown person on May 1, 2006, the day *before* Clark's execution, despite the written protocol's clear mandate

that the execution drugs were to be dispensed to Execution Team Members only on the day of the execution.¹³ And DRC Defendants had obtained only a total of two grams of sodium thiopental in advance of the Clark execution, contrary to the written execution protocol which required them to order a sufficient quantity of the execution drugs as a contingency against contamination or inadvertent loss of any of the drugs.¹⁴

1026. DRC Defendants injected two full syringes—with one gram in each syringe—into the bad IV line. This means that the drugs were not injected into Clark’s peripheral veins as required by the written Execution Protocol.

¹³ This deviation or variation also occurred for several other executions, including at least one execution in which the lethal drugs were dispensed at least two days before the execution date.

¹⁴ Defendants similarly deviated or varied with at least twenty-three other executions, including but not limited to executions of inmates Getsy, Keene, Fautenberry, Bryant-Bey, Cooey, Newton, Filiaggi, Lundgren, Wilson, Ferguson, Barton, Benner, Hicks, Willie Williams, Ashworth, William Smith, Dennis, Mink, Vrabel, Zuern, Wickline, Roe, and Lewis Williams.

1027. There were no further supplies of sodium thiopental in the Equipment Room. Only one additional gram of sodium thiopental was dispensed from the SOCF pharmacy for use in Clark's execution after the first IV site failed. Because of DRC Defendants' failures regarding the first peripheral IV administration site, and because they improperly started the execution with only two grams of sodium thiopental total, and used only three grams total, it was impossible for DRC Defendants to administer to Clark a full two grams via peripheral IV injection before they administered drugs two and three.
1028. Thus it is extremely likely that Clark was not properly rendered unconscious, unaware and insensate before he was subjected to injections of pancuronium bromide and potassium chloride, in turn subjecting Clark to excruciating, torturous pain during his execution
- Christopher Newton**
1029. DRC Defendants executed Newton on May 24, 2007, using a three-drug method.
1030. It took approximately twenty-two minutes to insert the first IV into Newton's arm.
1031. It took approximately one hour and fifteen minutes to place the second IV.
1032. Placing the IVs took so long that Newton had to take a short bathroom break.

1033. Upon information and belief, the drug administration to Newton was not in accordance with the written Execution Protocol because of the faulty IV lines, but his pain and suffering was masked by the paralytic drug.

Daniel Wilson

1034. DRC Defendants executed Daniel Wilson on June 3, 2009 using a three-drug method.

1035. Despite the mandate in the then-applicable May 14, 2009 written protocol that required assessment of the inmate's veins on the morning of the scheduled execution, DRC Defendants failed to conduct the required assessment of Wilson's veins the morning of the execution.

Marvellous Keene

1036. DRC Defendants executed Keene on July 21, 2009 using a three-drug method.

1037. The written protocol effective at the time explicitly required two functional IV sites at the start and during an execution, along with the related requirement that if one IV site became compromised, the execution must be stopped, if only to assess the situation.

1038. TM # 17 was the “executioner” and TM # 21 was the back-up executioner, and the observer on hand in the Equipment Room with TM # 17 for Keene’s execution. Those two individuals are still listed as the Drug Administrators for the Execution Team. Upon information and belief, TM # 17 and TM # 21 will be the Drug Administrators for Plaintiff’s execution.
1039. Both individuals were aware of a problem with one IV bag and line during the Keene execution. But they deviated or varied substantially from the written protocol when they chose to ignore the problem and forged ahead with the execution, rather than halting as the written protocol required. Thus, it is likely that Keene also suffered the excruciating pain of being injected with the second and third drugs while still conscious, aware and able to experience that pain.

Romell Broom

1040. DRC Defendants attempted to execute Romell Broom on September 15, 2009 using a three-drug method.
1041. Myriad deviations and/or variations from the written protocol during the Broom execution attempt, as Broom was subjected to torturous pain and suffering for over two hours.¹⁵

¹⁵ The facts surrounding the failed Broom execution attempt are thoroughly set out in the deposition testimony taken in the weeks following September 15, 2009. (See, e.g., Cooey, No. 2:04-cv-1156, ECF Nos. 580, 598, Broom Dep., Oct. 5, 2009, which is incorporated by reference here in full.)

1042. DRC Defendants failed to conduct the mandatory venous access assessments on Broom, just as they failed to do in the Wilson execution.
1043. Defendants, including TM # 9, TM # 17, and TM # 21 (each of whom are still the primary Medical Team members and expected to be the primary Medical Team members for Plaintiff's execution), unsuccessfully attempted to insert IV lines in eighteen different spots on Broom's body, making approximately fifty needle insertions over the course of two hours.
1044. Defendants attempted to establish an operable IV by repeatedly inserting IV catheters into the crooks of both of Broom's elbows (the antecubital area), his left biceps, his left wrist, the base of his thumb on each hand, over the knuckles on the back of his right hand, the top of his left foot, and his right medial malleolus (ankle bone on the inside part of the ankle).
1045. During Defendants' repeated attempts to establish and/or sustain IV access in Broom, venous access was obtained on at least two different occasions. Upon information and belief, at least one of those instances failed when execution team members mishandled the IV apparatus after establishing a successful IV hook-up, resulting in the IV catheter being yanked out of Broom's vein.

1046. In at least one other instance, execution team members established but then lost venous access by virtue of their actions following successful IV catheter insertion.
1047. Personnel involved in attempting to execute Broom included at least one physician, Dr. Carmelita Bautista. Dr. Bautista had never before been involved in an execution; she was not, and had never been, a member of the execution team, and she had never received any training in the execution protocol. Team Member # 9's reaction when Dr. Bautista entered the room is telling: "I look up and she's present [in the holding cell]. And I'm like, dear God, what is she doing here?"
1048. Judge Frost wrote: "That is a question that requires an answer." *Cooey (Smith) v. Kasich*, 801 F. Supp. 2d 623, 650 (S.D. Ohio 2011).
1049. At no time did DRC Defendants consider the pain and suffering that Broom was enduring as part of the discussion and factors for whether to halt the execution attempt. One Medical Team member testified that he was thinking about Broom's victim and the victim's family as he was repeatedly trying to obtain IV access.
1050. After two hours of Defendants causing substantial, torturous physical and psychological pain to Broom, DRC Director Terry Collins requested that Governor Ted Strickland grant a reprieve to postpone the execution process for one week.

1051. The only concern was for the execution team members' well-being, concern about generating future litigation, and concern about avoiding subsequent, more embarrassing problems if the execution continued and IV administration of the lethal drugs failed.
1052. Former Director Collins later testified that he did *not* recommend stopping Broom's execution out of concern for the physical and mental anguish that Broom was suffering.
1053. Instead, the decision was made based on three factors: (1) concern for the execution team; (2) Collins's belief, informed by discussions with the execution team members, that further attempts to gain venous access that day would be fruitless; and (3) Collins's concern that he would be "in a whole 'nother ballpark" of legal trouble if the team managed to establish two viable IV sites and started injecting the three drugs only to suffer yet another venous failure when they had no back-up plan. (*See* T. Collins Depo. at 30-38, 60-72; E. Voorhies Depo. at 138.)
1054. Broom, during the course of this two-hour ordeal, requested to speak with his counsel on at least one occasion and perhaps more. Defendants denied these requests, citing their execution policy, and then denied counsel's request to speak with Broom.
1055. At least one member of Broom's execution team explicitly stated that he was looking forward to seeing the State execute another particular inmate.

Vernon Smith, a.k.a., Abdullah Sharif Kaazim Mahdi

1056. Defendants executed Vernon Smith, a.k.a. Abdullah Sharif Kaazim Mahdi, on January 7, 2010, using a one-drug method.
1057. On the day of Smith's execution, TM # 17 was in the hospital, so he could not and did not participate in the execution.
1058. Only TM's # 9, # 17, and # 21 were qualified under the written protocol at that time to be part of the IV insertion team.
1059. TM # 9's participation ceases after the IVs are established.
1060. TM # 9 is not qualified under Ohio law to administer intravenous and intramuscular injections.
1061. Only TM's # 17 and # 21 were qualified under the written protocol to take numerous other actions related to the execution drugs which are reserved for members of the "medical" team.
1062. These tasks explicitly require certain qualifications under Ohio law, and also require the participation by not one but *two* such qualified execution team members.
1063. These tasks include procuring, taking possession of, preparing, verifying, injecting and administering, and disposing of the execution drugs, as well as monitoring and documenting all of the above.
1064. The written protocol required (and still requires) participation of at least two individuals with certain qualifications under Ohio law for these critical responsibilities, but this was impossible during the Smith execution, due to TM # 17's absence.

1065. Defendants used TM # 9 in TM # 17's place.
1066. Defendants ignored the explicit mandates of their written execution protocol by executing Smith without a second individual with the necessary qualifications under the written protocol present in the Equipment Room to supervise or monitor the drug preparation, administration, and other related tasks,
1067. Defendants also ignored the explicit mandates of their written execution protocol by involving TM # 9 in TM # 17's stead to execute Smith, because TM # 9 is not qualified under Ohio law to carry out the tasks in question.

Michael Beuke

1068. Defendants executed Michael Beuke on May 13, 2010, using a one-drug method.
1069. Approximately one month before the Beuke execution, TM #17 notified Defendants that he would be absent on the day of the execution, because he needed to attend a doctor's appointment.
1070. Defendants made no alternative arrangements to replace TM # 17 within the confines of the written protocol.
1071. Defendants did not change Beuke's execution date by way of a reprieve from the Governor.
1072. Instead, Defendants chose to use TM # 9 as a replacement for TM # 17 again, just as they did in the Vernon Smith execution.

1073. During the Beuke execution, therefore, Defendants engaged in all of the same or similar deviations or variations from the Vernon Smith execution recounted above.

Dennis McGuire

1074. Defendants executed Dennis McGuire on January 16, 2014, using a two-drug method including midazolam.

1075. Defendants were warned on numerous occasions in advance of McGuire's execution of the substantial likelihood that McGuire's body habitus presented a substantial likelihood that McGuire would obstruct and suffocate if subjected to Defendants' execution protocol using midazolam.

1076. In advance of McGuire's execution, Defendants exchanged emails with various medical professionals about how the two-drug method with midazolam would work. These emails and other documents revealed that Ohio was warned that these drugs could cause a prisoner to "gasp" and "hyperventilate" as he died, and that using these drugs to execute a person could end in "disaster," "a terrible, arduous, tormenting execution that is also an ugly visual and shameful spectacle," in part because, before losing consciousness, the patient likely would be "subjected to the intoxicating effects of these drugs,

- which include hallucinations.” Ben Crair, *Exclusive Emails Show Ohio’s Doubts About Lethal Injection*, NEW REPUBLIC, Aug. 17, 2014.¹⁶
1077. Despite additional and numerous warnings by McGuire’s counsel and expert witness, the pre-execution physical assessments carried out pursuant to Defendants’ execution protocol affirmatively stated that there were no problems that might affect the execution, and/or failed to note any possible problems that might affect the execution.
1078. Despite the warnings about the grave likelihood of problems that would arise during the McGuire execution if Defendants used midazolam and hydromorphone to kill McGuire, Defendant Mohr made public statements before the execution declaring to the effect that he was not worried and was confident there would be no problems at all.
1079. Despite significant warnings of impending problems with McGuire’s execution, Defendants took no actions to have any kind of resuscitative measures on hand or in place in the Death House before they proceeded with the execution.

¹⁶ Available at <http://www.newrepublic.com/article/119068/exclusiveemails-reveal-states-worries-about-problematic-execution>.

1080. Defendant Mohr and/or Defendant Gray explicitly confirmed just minutes before starting the execution of McGuire that Defendants had not put into place any kind of resuscitative measures and had no plan to do so for McGuire's execution.
1081. Approximately 26 minutes elapsed between the time when Defendants injected McGuire and when Defendant Warden Morgan declared the time of death.
1082. A death occurring over approximately 26 minutes is a lingering death.
1083. There is a substantial risk that McGuire remained clinically and statutorily alive at the time Defendant Warden Morgan declared him dead.
1084. There is a substantial risk that McGuire remained clinically alive for as long as 45 more minutes after the Warden announced a time of death.
1085. A death occurring over approximately 70 minutes is a lingering death.
1086. Even assuming that McGuire was clinically and statutorily dead at the time Defendant Warden Morgan declared him dead, McGuire suffered a lingering death as a result of Defendants' application of 01-COM-11.
1087. Descriptions of the scene in the death chamber during following Defendants' injection into McGuire of midazolam and hydromorphone characterized the scene as "ghastly," "disturbing," "inhumane," and horrendous as McGuire slowly suffocated to death while the

midazolam suppressed his respiratory response. As one witness described the scene: “he was fighting for breath, and I could see both of his fists were clenched the entire time. His gasps could be heard through the glass wall that separated us. Towards the end, the gasping faded into small puffs of his mouth. It was much like a fish lying along the shore puffing for that one gasp of air that would allow it to breathe.” Lawrence Hummer, “*I witnessed Ohio’s execution of Dennis McGuire. What I saw was inhumane,*” The Guardian (January 22, 2014).¹⁷

1088. Another witness described the scene as follows:

Things appeared to be going as planned until about five minutes after the chemical cocktail began flowing into [McGuire’s] veins. The state was using a two-drug combination that had never previously been used in the U.S. Suddenly, he began to gasp and appeared to choke. A minute later, he gasped so deeply that his stomach heaved up and down. It continued for nearly 15 minutes. McGuire clenched his fists repeatedly and several times appeared to try to rise up off the table, only to be prevented by the restraints on his chest and arms. His grown son and daughter looked on in horror, sobbing uncontrollably. The family members of Joy Stewart, the pregnant, 22-year-old victim, watched in stunned silence.

¹⁷Available at <http://www.theguardian.com/commentisfree/2014/jan/22/ohio-mcguire-execution-untested-lethal-injection-inhumane>.

- Alan Johnson, *Dispatch reporter has watched twenty men die*, COLUMBUS MONTHLY (August 2016 ed.).¹⁸
1089. McGuire’s death was a spectacle, undignified, disgraceful execution as a result of Defendants’ 01-COM-11, as written and as applied to him.
1090. Despite these objective descriptions, Defendants’ formal paperwork related to the McGuire execution fails to acknowledge the spectacle that unfolded in the death chamber.
1091. The “Timeline Log” that is supposed to document everything significant that occurs during Defendants’ execution process contains no entries describing what occurred in the death chamber between the time when the continuous flush of saline solution started at 10:28:28 and when Drug Administrator # 23 entered the death chamber to “make an assessment” of McGuire at 10:48:47.
1092. The After-Action Review document completed on January 16, 2014 immediately following the McGuire execution included the question “Were there acts or events that were identified in advance as anticipated contingencies; if so, did those things occur?” The official answer in the January 16, 2014 After-Action Review was “No.”

¹⁸ Available at <http://www.columbusmonthly.com/content/stories/2016/08/these-eyes-have-watched-twenty-men-die.html>.

1093. The January 16, 2014 After-Action Review included the following question: “Were there acts or events that were not anticipated in advance?” Answer: “No.”
1094. The January 16, 2014 After-Action Review included the following question: “How well did the process work? Should changes to the process be considered?” Answer: “The process worked very well and the execution was carried out in compliance with 01-COM-11.”
1095. The “Executive Summary” completed on April 28, 2014 regarding McGuire execution asserts that McGuire’s execution was “humane, dignified and [done in a] lawful manner.”
1096. The Executive Summary allowed only that “[s]everal minutes after the administration of the[] drugs, McGuire appeared to be unconscious and exhibited some irregular movements in his abdomen and mouth,” while subsequently reasserting that Defendants “remain[] confident in [their] belief that the McGuire execution was carried out consistent with DRC’s policies and constitutional requirements.” There was no assessment of whether McGuire was conscious, aware and sensate while he slowly suffocated to death.
1097. The “After-Action Review” completed on April 28, 2014 also asserted that McGuire “was not conscious beginning a few minutes after the drugs were administered. He did not experience pain, distress or air hunger after the drugs were administered or when the bodily movements and sounds occurred. Therefore, his execution was

- conducted in a constitutional manner consistent with the Policy.” The “After-Action Review” provided no scientific basis for making the above assertions.
1098. Upon information and belief, the persons who conducted the “investigation” into the McGuire execution and declared that there were problems with it have previously been involved in defending this case or similar cases.
1099. Upon information and belief, the “investigators” spoke only with DRC employees, including some Defendants and Defendants’ expert witness, Dr. Dershwitz, in the course of their “investigation.” They did not speak to other third-party or otherwise objective eyewitnesses who had no incentive to whitewash the official version of the McGuire execution.
1100. McGuire’s execution was the first in a series of high-profile botched executions that involved midazolam. *See, e.g.*, Associated Press, “Three executions gone wrong: Details of lethal injections in Arizona, Ohio, Oklahoma,” Mercury News (July 24, 2014).
1101. During McGuire’s execution, Ohio was required by the execution protocol then in effect to inject McGuire with 40 mg. of hydromorphone and 10 mg. of midazolam.
1102. Upon information and belief, Ohio injected McGuire with an amount of hydromorphone other than 40 mg.

1103. Upon information and belief, Ohio injected McGuire with an amount of midazolam other than 10 mg.

Ronald Phillips

1104. Defendants executed Ronald Phillips on July 26, 2017, using a three drug method with 500 mg. midazolam as the first drug, followed by 1000 mg. of Rocuronium Bromide, followed by 240 meq. of potassium chloride.

1105. Defendants were extensively warned in advance of that execution that midazolam would be insufficient to protect Phillips against the severe pain caused by injection and the functioning of the second and third drugs.

1106. The Execution Timeline Log for Defendants' execution of Ronald Phillips on July 26, 2017, establishes that Defendants completed injection of midazolam at 10:33:03, and began injection of the paralytic drug at 10:34:42—1 minute and 39 seconds after the Drug Administrators finished injecting the midazolam.

1107. By administering the paralytic so rapidly, Defendants effectively precluded witnesses from observing the behaviors and actions that have been consistently reported in states in which midazolam has been used without a paralytic or with a paralytic injected after a waiting period of several minutes.

1108. After being injected with midazolam, but before administration of the paralytic, Phillips exhibited signs consistent with struggling to breathe.
1109. Just before the midazolam was administered, Phillips's mouth was moving and he appeared to be mouthing a prayer.
1110. Once the Warden gave the signal to inject the first drug, midazolam, Phillips's mouth slowed and then stopped moving altogether.
1111. Phillips's face relaxed for a short time, with his eyes remaining closed but less tightly shut than before.
1112. His jaw also slackened, and his mouth opened as a result.
1113. There were no discernable movements of any kind for a few seconds, just a very quick, fleeting period of time.
1114. Phillips appeared to be snoring for a few moments, but then his mouth began opening and closing consistent with a "fish out of water" appearance.
1115. His stomach heaved a few times and his mouth was continuing to move in the rhythmic fashion, opening and closing, opening and closing.
1116. These movements were precisely the same in their form and intensity throughout the duration of the consciousness check and immediately thereafter.
1117. Those bodily movements were not his stomach or chest moving in an up and down/in and out fashion consistent with taking in and

breathing out air, but rather actions and movements more consistent with someone gasping for breath, fighting to breathe.

1118. While his mouth movements were rhythmic and consistent in pace, the movements of his chest/stomach area was more sporadic.

Phillips continued to exhibit these movements throughout the execution until the paralytic was administered and took effect.

1119. The effect of the paralytic was evident because all of Phillips's movements very quickly ceased; it was a near total cessation on-setting very rapidly, as opposed to a more gradual relaxation.

1120. Additionally, Phillips's hands were in noticeably different repose. During the course of the execution, his right hand became more tightly closed (yet not fully clenched), while his other hand was more flat but with curled fingers.

1121. TM # 21 conducted the “consciousness checks” on Phillips. Those checks entailed speaking softly into Phillips's left ear; lifting his left eyelid and peering into Phillips's eye for approximately 2 seconds; and pinching somewhere on Phillips's left hand.

1122. The “consciousness checks” were completed in less than 28 seconds, because only 28 seconds elapsed between the time TM #21 entered the death chamber and when he exited the chamber.

1123. The “consciousness checks” were assessing for reflexive movement.

1124. Checking for reflexive movement is not a reliable method to ensure that an inmate is sufficiently unconscious, unaware and insensate to

not be exposed to the excruciating physical and mental pain and suffering caused by the injection of the second and third drugs and the process of dying from those drugs.

Gary Otte

1125. Defendants executed Gary Otte on September 13, 2017, using a three drug method with 500 mg. midazolam as the first drug, followed by 1000 mg. of Rocuronium Bromide, followed by 240 meq. of potassium chloride.
1126. Defendants were extensively warned in advance of that execution that midazolam would be insufficient to protect Otte against the severe pain caused by injection and the functioning of the second and third drugs.
1127. The Execution Timeline Log for Defendants' execution of Otte on September 13, 2017 establishes that Defendants completed injection of midazolam at 10:42:13 a.m., and began injection of the paralytic drug at 10:43:23—1 minute and 10 seconds after the Drug Administrators finished injecting the midazolam.
1128. By administering the paralytic so rapidly, Defendants effectively precluded witnesses from observing the behaviors and actions that have been consistently reported in states in which midazolam has been used without a paralytic or with a paralytic injected after a waiting period of several minutes.

1129. Shortly after being injected with midazolam, Otte began exhibiting signs consistent with his airway obstructing. Otte exhibited these signs of obstruction up to the point when he attempted to take his last breath when the paralytic halted his attempts to breathe.
1130. After being injected with midazolam, but before administration of the paralytic, Otte exhibited signs consistent with remaining or having regained consciousness, awareness, or sensation. His stomach was reported to be heaving up and down as he struggled to breathe, and his hands were clenched.
1131. Otte's eyes never closed fully during or after his execution. His eyes remained at least partly open throughout the ordeal.
1132. Approximately one to two minutes after the midazolam injections began, Otte began producing active tears such that tears were pouring out of his eyes and down his cheeks. He was not producing active tears, nor was he crying in the sense of an emotional response to the execution or impending death, before the midazolam was injected, nor in the immediate seconds that followed.
1133. As Otte began to obstruct, however, he began profusely producing active tears.
1134. This active tear production continued throughout the time that Defendants conducted their "consciousness check" and for approximately 45 seconds to one minute after Defendants exited the death chamber after the "consciousness check."

1135. No until after the paralytic was injected and his body was paralyzed and bodily functions frozen did Otte stop producing active tears.
1136. A person who is under anesthesia no longer produces tears.
1137. A person who is insensate to severe pain does not actively produce tears upon being subjected to severely painful stimuli.
1138. Active tear production is a sign Otte was experiencing severe pain and suffering, meaning Otte was conscious, aware, and/or sensate to severe pain and suffering after he was injected with 500 mg. of midazolam, after Defendants conducted their “consciousness check” and determined Otte was unconscious, and at the time he was injected with the paralytic and potassium chloride.
1139. Thus, it is sure or very likely that Otte was conscious, aware, and/or sensate to the severe pain and suffering he experienced during his execution using Defendants’ execution protocol, which includes the drugs used, the insufficient safeguards, the inadequate assessments of consciousness, awareness and sensation, lack of genuine technological means of such assessments, the use of midazolam as the critical first drug, and injection of the paralytic drug at an extremely rapid time after injection of the midazolam.
1140. After Otte was brought into the death chamber, witnesses on behalf of Otte stood up from their seats in the witness area to better observe what was happening in the death chamber.

1141. When those witnesses stood up, Defendants or their agents ordered the witnesses to sit down and/or to remain seated.
1142. When Otte began to visibly obstruct, Attorney Carol Wright, one of Otte's appointed counsel and one of his designated execution witnesses, arose from her seat and attempted, consistent with the explicit terms of 01-COM-11, ¶ VI.G.2, to exit the witness area to use the phone mounted on the Death House wall outside the witness area, in order to call to the "waiting room" to reach Attorney Allen Bohnert, who would then be able to contact the court.
1143. Rather than the "free access" to the phone guaranteed by 01-COM-11, however, Attorney Wright was prevented from leaving the witness area by Defendants or their agents, both by verbal instruction that Wright was not permitted to leave and by virtue of locking the door between the witness area and the hallway where the phone is mounted.
1144. Attorney Wright's name had been previously provided to Defendants as a witness in advance of Otte's execution, such that her identify was verified before she was authorized to enter the SOCF facility on the day of the execution.
1145. Defendants prevented Attorney Wright from accessing the Death House telephone for approximately two minutes or more, such that she was only able to access the phone during the period when Defendants performed their "consciousness check" on Otte and then

began injecting the paralytic drug, arresting any further outward expressions of his obstructing and active tear production.

1146. Thus, by preventing Attorney Wright from accessing the telephone at a critical point during the execution, Defendants prevented Otte's counsel from being able to contact the court in time sufficient to prevent administration of the paralytic drug before Otte was unconscious, unaware and insensate to severe pain and suffering.
1147. The execution timeline log states that Defendants had entered the death chamber to perform the "consciousness check" at or around 10:43:09 a.m., and that they exited the death chamber after completing the "consciousness check" at or around 10:43:31 a.m.
1148. That timing establishes that Defendants spent no more than approximately 12 seconds performing the critical "consciousness check" on Otte.
1149. Upon information and belief, TM # 17 performed the "consciousness check" on Otte.
1150. While TM # 17 performed the "consciousness check," TM # 21 took up a position between Otte's left arm and the side of his body, in an apparent attempt to obstruct witnesses from observing the "consciousness check" and/or any response from it.
1151. Defendants only performed a single "consciousness check" on Otte; TM # 17 lifted Otte's left eyelid, and peered into his eye.

1152. The full extent of the “consciousness checks” on Otte took no more than approximately 5 seconds.
1153. TM # 17 did not touch the sclera of Otte’s left eye, or any other part of his eye during the “consciousness check.”
1154. TM # 17 did not lean over to Otte’s ear to perform the “verbal” “consciousness check,” nor did he audibly or visibly say Otte’s name.
1155. TM # 17 did not perform the verbal “consciousness check.”
1156. TM # 17 did not perform the “nail bed” “consciousness check.”
1157. The “Medical Team Checklist – Execution” document, DRC Form 4083, from the Otte execution falsely documents that the Execution Team members made one attempt to establish an IV on the left arm, and one attempt on the right arm.
1158. The “Master Checklist” document, DRC Form 4085, from the Otte execution falsely documents that the Execution Team members made one attempt to establish an IV on the left arm, and one attempt on the right arm.
1159. The execution protocol requires Defendants to accurately report and “capture” on the official execution timeline log the number of IV insertion attempts on each arm.
1160. The execution timeline from Otte’s execution falsely documents that the Execution Team members made one attempt to establish an IV on the left arm, and one attempt on the right arm

1161. The Execution Team members made at least two attempts to gain IV access on Otte's right arm, so it is not true that the Execution Team members made one attempt to obtain IV access on Otte's right arm.
1162. The "Medical Team Checklist – Execution" document from the Otte execution falsely documents that the Medical Team performed the "Verbal," "Eye" and "Nail Bed" "consciousness checks" on Otte.
1163. It is not true that the Medical Team performed all three of those checks on Otte, nor is it true that TM # 17 touched the sclera of Otte's eye as would be suggested by documenting the "Eye" test.
1164. Upon information and belief, TM # 21 filled out the "Medical Team Checklist – Execution" for the Otte execution.
1165. Upon information and belief, TM # 21 or another Defendant filled in the information about the "consciousness checks" purportedly done on Otte at a time other than immediately after TM # 21 and TM # 17 exited the death chamber after TM # 17 lifted Otte's eyelid and peered into his eye.

Additional Ohio Executions

1166. In addition to the deviations from execution policies and execution protocols identified herein, Defendants have deviated and varied from the execution policies and execution protocol during the executions of Kenneth Biros, Mark Brown, Lawrence Reynolds, Darryl Durr, William Garner, Roderick Davie, Michael Benge, Frank Spisak, Johnnie Baston, Reginald Brooks, and others.
1167. This includes, but is not limited to, deviations and/or variations regarding execution policy and written protocol mandates governing who may, and who must, participate at various points in the execution; deviations and/or variations related to acquisition, possession, distribution, delivery, and administration of the execution drugs; deviations and/or variations related to training requirements and/or execution rehearsals; deviations and/or variations from one or more of the five “core” elements of the written protocol, and deviations from other “non-core” elements of the written protocol.

William Morva

1168. On July 6, 2017, the State of Virginia executed William Morva using a three drug combination that included IV injection of 500 mg. midazolam, followed by a paralytic agent and then potassium chloride.
1169. Under Virginia’s execution protocol, execution team members inject the paralytic agent approximately two minutes after injecting the

- midazolam, during which time a “noxious stimuli” test will be performed. Thus, the “noxious stimuli” test will be performed less than two minutes following injection of the midazolam.
1170. Following injection of the midazolam, Morva made a loud noise that sounded like a hiccup, and there were several sharp contractions of his abdomen.
1171. Morva’s deep breathing and nodding of his head continued for at least two minutes.
1172. At that point, he appeared to be speaking. Then he was injected with the paralytic and the chemical curtain concealed all further visible evidence of his level of consciousness, awareness and sensation.
- Kenneth Williams**
1173. On April 27, 2017, the State of Arkansas executed Kenneth Williams using a three-drug combination that included IV injection of 500 mg. midazolam, 100 mg. vecuronium bromide, and 240 meq. potassium chloride.
1174. Arkansas’s execution protocol requires that at least five (5) minutes have elapsed before the “consciousness check” is conducted and any subsequent drugs are injected.
1175. Multiple media witnesses described seeing Williams “coughing, convulsing, lurching, jerking” for a period of at least 10 to 20 seconds, “lurch[ing]” 15 times in “quick succession, followed by five slower lurches, three minutes after the” midazolam was injected. Phil

McCausland, *Arkansas Execution of Kenneth Williams ‘Horrifying,’:*

Lawyer, NBC News, Apr. 27, 2017.¹⁹

1176. Williams was described as “jerk[ing] 15 times in quick success—lurching violently against the leather restraint across his chest—then the rate slowed for a final five moments.” Kelly P. Kissel & Andrew Demillo, *Arkansas inmate convulses during deadline-beating execution*, Desert News, April 28, 2017.²⁰
1177. The same witnesses stated that Williams’s moaning and movements were so loud they “could be heard after the microphone to the death chamber was turned off.” McCausland, *supra*; see also Kelly Kissel, *Timeline of latest Arkansas execution from AP reporter*, AP, Apr. 28, 2017.²¹
1178. Williams was reported to have “breathed through his mouth and moaned and groaned once—during a consciousness check—until falling still seven minutes after the” midazolam injection. *Id.*

¹⁹ Available at <http://www.nbcnews.com/storyline/lethal-injection/arkansas-executes-kenneth-williams-4th-lethal-injection-week-n752086>.

²⁰ Available at <http://www.deseretnews.com/article/765693914/Arkansas-inmate-convulses-during-deadline-beating-execution.html>.

²¹ Available at <https://www.apnews.com/88dbdd478f504dfb92106478ab1b9e3c>.

1179. Williams did not cease breathing heavily until approximately 6 minutes after injection of the midazolam, when it is likely the paralytic was injected to stop all movement. Kissel, *supra*.
1180. A post-execution autopsy report summary noted that Williams's external nares and oral cavity contained serosanguineous fluid, which means bodily fluid that was mixed with blood.
1181. The same summary report noted that Williams's upper and lower airways contained serosanguineous fluid as well.

Marcel Williams

1182. On April 24, 2017, the State of Arkansas executed Marcel Williams using a three-drug combination that included IV injection of 500 mg. midazolam, 100 mg. vecuronium bromide, and 240 meq. potassium chloride.
1183. After being injected with midazolam at 10:16 p.m., Williams's "eyes began to droop and eventually closed (the right one lingered slightly open throughout). His breaths became deep and heavy. His back arched off the gurney as he sucked in air." Jacob Rosenberg, *Arkansas executions: 'I was watching him breathe heavily and arch his back'*, The Guardian, April 25, 2017.²² Williams "moved in such a way, rising off the gurney" numerous times. *Id.* "[A]t 10:21 p.m.,

²² Available at <https://www.theguardian.com/us-news/2017/apr/25/arkansas-execution-eyewitness-marcel-williams>.

Williams was still breathing heavily and moving. At this point, it is likely another dose of midazolam was given.” *Id.* Williams was breathing heavily and arching his back, and “then the breathing began to shallow out. By 10:24 p.m., Williams looked completely still.” *Id.*

1184. A post-execution autopsy report summary noted that Williams’s external nares and oral cavity contained watery secretions.
1185. The same summary report also noted that Williams’s upper and lower airways contained abundant amount of watery secretions.

Jack Jones

1186. On April 24, 2017, the State of Arkansas also executed Jack Jones using a three-drug combination that included IV injection of 500 mg. midazolam, 100 mg. vecuronium bromide, and 240 meq. potassium chloride.
1187. During his execution, Jones was moving his mouth and gulping for air about five minutes into the execution. Associated Press, *Witnesses disagree about Jack Jones’ execution*, Apr. 26, 2017.²³

²³ Available at <http://www.4029tv.com/article/witnesses-disagree-about-jack-jones-execution/9565524>.

1188. Jones's chest was continuously rising five minutes into the execution.

Associated Press, *Timeline of Arkansas Execution From AP Reporter*,
Apr. 25, 2017.²⁴

1189. A post-execution autopsy report summary noted dependent congestive changes and mild diffuse edematous changes in Jones's respiratory system.

Lendell Lee

1190. On April 20, 2017, the State of Arkansas executed Lendell Lee using a three-drug combination that included IV injection of 500 mg. midazolam, 100 mg. vecuronium bromide, and 240 meq. potassium chloride.

1191. A post-execution autopsy report summary noted a moderate amount of thick, white frothy fluid is easily expressed from all lobes of his lungs upon manual compression.

Ricky Gray

1192. On January 18, 2017, the State of Virginia executed Ricky Gray using a three-drug protocol that included IV injection of 500 mg. midazolam, followed by a paralytic agent and then potassium chloride.

²⁴ Available at http://www.apnewsarchive.com/2017/Timeline_of_Arkansas_execution_from_AP_reporter/id-cc68b8ef818242599585f9148055a7fe.

1193. Gray had labored breathing and was moving slightly for at least a few minutes after injection of the midazolam, before he was stilled by injection of the paralytic.
1194. Gray's legs were moving, and he was snoring loudly, his chest moving, rising and falling, rising and falling.
1195. Gray took a number of deep breaths and appeared to make snoring or groaning sounds in the minutes after the midazolam was injected.
1196. Those movements were halted by injection of the paralytic agent.
1197. A post-execution autopsy of Gray showed anatomic changes in his lungs that are more often seen in the aftermath of a sarin gas attack than in a routine hospital autopsy.
1198. This is of particular concern given the fact that midazolam is not an anesthetic, but rather a sedative typically used for medical procedures requiring conscious sedation.
1199. A frothy liquid found in Gray's upper airways indicated that he suffered an acute pulmonary edema.
1200. Blood found on Gray's lips indicates that blood entered Gray's lungs while he was still breathing. This would be an experience akin to drowning from within.
1201. Severe pulmonary edema is an intolerable, horrific way of dying that will subject the inmate to significant panic and terror during the process of dying.

Ronald Smith

1202. On December 8, 2016, the State of Alabama executed Ronald Smith using a three-drug combination that included IV injection of 500 mg. midazolam, 600 mg. rocuronium bromide, and 240 mq. potassium chloride.
1203. During the execution of Ronald Smith, he was moving his arms, clenching his hand or hands, attempting to talk, coughing, and attempting to move for approximately fifteen minutes after being injected with 500 mg. of midazolam.
1204. Smith was moving his head, hands and arms, coughing, and attempting to speak before and after the first “consciousness check.” Smith moved his arm toward his body (away from the pinch) when he was pinched as part of the first “consciousness check.”
1205. From about 10:34 to 10:47, Smith appeared to be struggling for breath and heaved and coughed and clenched his left fist after apparently being administered the first drug in the three-drug combination. At times his left eye also appeared to be slightly open.
1206. Two “consciousness checks” were performed on Smith. The “consciousness tests” consisted of the corrections officer calling out Smith's name, brushing his eyebrows back, and pinching him under his left arm.

1207. Smith reopened his eyes after a prison official performed a second "consciousness check" by pushing his eyelid closed. He also moved his arm after the second consciousness check.
1208. Upon information and belief, Smith was injected with a second dose of 500 mg. of midazolam approximately five minutes after the first injection, while he was still exhibiting the above-described behaviors.
1209. There were two periods in which Smith appeared to rest somewhat briefly, as if in reaction to something.
1210. Smith appeared still immediately following the injection(s) of midazolam. His movements did not start manifesting until a few minutes later.
1211. Those periods of stillness immediately following the injections of midazolam were followed by coughing, heaving, flailing, or attempting to flail his arms, clenching and unclenching of his fists, movement of his lips, trouble breathing as if he was hyperventilated, and an asthmatic-sounding, barking cough.
1212. It took approximately 35 minutes before Smith was declared dead following the first injection. He heaved, moved and coughed for approximately 13 minutes during that time.

Christopher Brooks

1213. On January 21, 2016, the State of Alabama executed Christopher Brooks using, upon information and belief, a three-drug combination

that included IV injection of 500 mg. midazolam, 600 mg. rocuronium bromide, and 240 mq. potassium chloride.

1214. Upon information and belief, under Alabama's execution protocol, the executioners must wait until at least five minutes after injection of midazolam to perform a "consciousness" check before further injecting any of the second and third drugs. Following the "consciousness" checks and Brooks being declared "unconscious," Alabama officials injected the paralytic drug and potassium chloride.
1215. But according to an eyewitness account, Brooks opened his left eye after he was deemed "unconscious" and the second and third drugs were injected. Brooks never closed his eye after that. His breathing became very rapid, his chest heaving up and down, up and down, up and down.
1216. An autopsy conducted on Brooks diagnosed him as suffering a pulmonary edema, with the major bronchi containing froth, and the lungs containing a dark red-blue, moderately congested parenchyma oozing large amounts of yellow-tinged frothy fluid.

Clayton Lockett

1217. On April 14, 2014, the State of Oklahoma adopted a new execution protocol that included the use of IV injection of 100 mg. midazolam as the first of a three-drug injection sequence.

1218. On April 29, 2014, just over three months after Defendants executed McGuire, the State of Oklahoma executed Clayton Lockett using a three-drug method that included IV injection of 100 mg. midazolam as the first drug, followed by a paralytic drug and potassium chloride.
1219. Lockett was not declared dead until 43 minutes after the start of his execution.
1220. Although Lockett initially appeared to be “unconscious,” he was still conscious, aware, sensate and struggling to speak more than 20 minutes after the drugs had been administered. He was reported as saying “Man,” “I’m not,” and “something’s wrong.” Witnesses also reported that Lockett, at points, was “twitching” and “convulsing” so violently that “it looked like his whole upper body was trying to lift off the gurney.” Greg Botelho and Dana Ford, *Oklahoma stops execution after botching drug delivery; inmate dies*, CNN (Oct. 9, 2014).²⁵
1221. Officials then drew the blinds and discovered that the femoral catheter that was placed by the physician-executioner had, at some point during the execution, failed. Rather than flowing through his veins, some of the drugs eventually massed in Lockett’s tissue, creating a swelling under his skin “smaller than a tennis ball, but larger than a golf ball.” Because the insertion point had been

²⁵ Available at <http://www.cnn.com/2014/04/29/us/oklahoma-botched-execution/>.

obscured from the view of both the witnesses and the physicians, no one had noticed the swelling earlier. The physician-executioner then tried to insert the IV into Lockett's left femoral vein, but penetrated Lockett's femoral artery instead, spraying himself with blood. After all of this, the physician-executioner reported that Lockett's heart was still beating. At that point, the execution was called off after receiving permission from Governor's counsel, 33 minutes after it had begun. Ten minutes later, Lockett died. Upon information and belief, execution officials never tried to take emergency resuscitative actions for Lockett.

1222. In many ways, the execution of Lockett was a replay of what Ohio had done to Joseph Clark as well as Dennis McGuire. Lockett struggled, writhed, grimaced, kicked, bucked, shook, arched his back, tried to sit up, jerked, and gasped, even after he was allegedly "unconscious." *See generally, Warner v. Gross*, Case No. 5:14-cv-665, ECF No. 159, Plaintiffs' Proposed Findings of Fact and Conclusions of Law, at p. 10–44 of 83 (W.D. Okla. Dec. 12, 2014) (describing the horrific scene that unfolded during Lockett's execution); *see also* Cary Aspinwall & Ziva Branstetter, *Botched execution described as 'a bloody mess,' court*

filings shows, TULSA WORLD (Dec. 14, 2014)²⁶; Katie Fretland, *Scene at botched Oklahoma execution of Clayton Lockett was ‘a bloody mess’*, THE GUARDIAN (Dec. 13, 2014)²⁷.

1223. Oklahoma officials who participated in or witnessed the execution described the scene as “like a horror movie,” and that “shit’s fucking with me.” *Warner v. Gross*, *supra*, Plaintiffs’ Proposed Findings of Fact and Conclusions of Law, at p. 43 of 83. A member of the execution team described the entire Lockett execution as a “cluster.” *Id.*
1224. All of this demonstrates that Lockett’s death was painful, lingering, undignified, and inhumane.
1225. Even though there was extensive evidence of infiltration or some other IV administration failure, an official autopsy report concluded that the concentration of midazolam located in Lockett’s blood, even after the delay until an autopsy was performed, was still greater than the therapeutic level necessary to render an average person unconscious.

²⁶ Available at http://m.tulsaworld.com/news/investigations/botched-execution-described-as-a-cluster-court-filing-shows/article_a4b70b76-84f7-5ebd-a5f3-044c205d474a.html?mode=jqm.

²⁷ Available at <http://www.theguardian.com/world/2014/dec/13/botched-oklahoma-execution-clayton-lockett-bloody-mess>.

See Oklahoma Department of Public Safety, The Execution of Clayton Lockett, Case No. 14-0189SI, at 14.²⁸

1226. Toxicology reports also demonstrated a significant level of midazolam in Lockett's brain tissue despite the incompetent IV injection. Thus, the Lockett execution demonstrates how unsuitable midazolam is as the first drug of a three-drug execution method involving a paralytic drug and potassium chloride.
1227. Additionally, because the paralytic drug's masking effect was substantially delayed by virtue of being injected into tissue in Lockett's execution rather than directly into the blood stream, the Lockett execution vividly demonstrates what Plaintiff and others will experience behind the veil of paralysis, namely, being conscious, aware or at least sensate when injected with the excruciating second and third drugs after midazolam.
1228. Ohio was directly involved in the Lockett execution because, following the McGuire execution, the "General Counsel in Ohio" provided advice to officials in Oklahoma, encouraging Oklahoma's use of midazolam as an execution drug and downplaying any concerns from Ohio's experience during the McGuire execution. *See Warner v. Gross*, Case

²⁸ Available at <http://deathpenaltyinfo.org/documents/LockettInvestigationReport.pdf>.

No. 5:14-cv-665, ECF No. 159, Plaintiffs' Proposed Findings of Fact and Conclusions of Law, at p. 8–9 of 83 (W.D. Okla. Dec. 12, 2014).

1229. According to Michael Oakley, the General Counsel for Oklahoma's Department of Corrections at or around the time Oklahoma adopted its execution protocol that included midazolam, "General Counsel in Ohio" consulted with him about midazolam after Ohio executed McGuire. *Id.* This was also reported in the media: "Oakley asked his counterpart in Ohio about the state's experience with midazolam. The media had exaggerated the problems, he was told. Yes, the new drug took a little longer to put a person to sleep, but it wasn't as bad as everyone was saying." Jeffery E. Stern, *The Cruel and Unusual Execution of Clayton Lockett*, THE ATLANTIC (June 2015).
1230. So rather than warn others about the horrifying scene that was likely to unfold if a state used drugs in a lethal-injection execution similar to what Defendants had recently experienced with the McGuire execution, Defendants downplayed, discounted and ignored what occurred during the McGuire execution in consultation with officials in other states who were considering following Ohio's lead.

Joseph Wood

1231. On July 23, 2014, about six months after McGuire's botched midazolam two-drug execution, and just three months after Lockett's botched midazolam three-drug execution, the State of Arizona decided to use an execution protocol comprised of 50 mg. midazolam and 50 mg. hydromorphone injected intravenously to execute Joseph Wood.
1232. Following McGuire's execution, Ohio had increased the dosage of each drug, despite the fact it publicly maintained that nothing out of the ordinary, unanticipated or unexpected occurred during McGuire's execution. The dosage of midazolam and hydromorphone required by Arizona's execution protocol used on Wood was the exact same amount of those drugs adopted by Ohio, as announced in its April 2014 "After Action Review" of McGuire's execution and associated revision of 01-COM-11.
1233. Upon information and belief, Arizona adopted its revised execution protocol after Arizona officials considered Ohio's execution protocol used to execute McGuire.
1234. The execution of Wood lasted almost two hours between the start of the first injection and when Wood was pronounced dead. It was the longest lethal injection execution in United States history.
1235. During that two hours, Wood suffocated to death in a procedure that Senator John McCain described as a "bollocks-upped situation" that

- “[was] torture.” Burgess Everett, *John McCain: Arizona execution ‘torture’*, POLITICO (July 24, 2014).²⁹
1236. One witness to the execution described Wood as “drowning in air,” as suffering “death by apnea,” and as gasping for air at least 640 times: Wood “gulped like a fish on land. The movement was like a piston: The mouth opened, the chest rose, the stomach convulsed. And when the doctor came in to check on his consciousness and turned on the microphone to announce that Wood was still sedated, we could hear the sound he was making: a snoring, sucking, similar to when a swimming-pool filter starts taking in air, a louder noise than I can imitate, though I have tried.” Michael Kiefer, *Reporter describes Arizona execution: 2 hours, 640 gasps*, ARIZONA REPUBLIC (July 26, 2014).³⁰
1237. Arizona officials injected Wood with fifteen syringes of the midazolam/hydromorphone mixture over the course of the execution. That means Wood was injected with a total of 750 mg. of hydromorphone and 750 mg. of midazolam, well above the 200 mg. ceiling effect level.

²⁹Available at <http://www.politico.com/story/2014/07/john-mccain-arizona-execution-109350>.

³⁰ Available at <http://www.azcentral.com/story/news/arizona/politics/2014/07/24/arizona-execution-joseph-wood-eyewitness/13083637/>.

Charles Warner

1238. On January 15, 2015, Oklahoma executed Charles Warner.
1239. His last words were that his “body [wa]s on fire.” Andrew Buncombe, *Charles Warner execution: Oklahoma inmate’s last words are ‘my body is on fire’ as state carries out first death penalty in nine months*, INDEPENDENT (Jan. 15, 2015).³¹
1240. Despite having represented to Warner’s counsel and, later, to the United States Supreme Court, that Warner was executed with a combination of midazolam, rocuronium bromide, and potassium chloride, Oklahoma’s representations were later found to be false.
1241. Rather than using potassium chloride, it was later revealed, the state somehow instead used potassium acetate. That inexplicable mistake—which, not without irony, occurred during litigation about Oklahoma’s claims of secrecy over the source and identity of the drugs it uses in executions—became apparent only after Oklahoma attempted to execute another prisoner, Richard Glossip, on September 30, 2015, again using potassium acetate.

³¹ Available at <http://www.independent.co.uk/news/world/americas/charles-warner-execution-my-body-is-on-fire-9981842.html>.

Kelly Gissendaner

1242. On or about March 2, 2015, the State of Georgia intended to execute Kelly Gissendaner using compounded pentobarbital, but ultimately postponed the execution because of problems with the compounded pentobarbital.
1243. The pentobarbital to be used was sent to an independent testing laboratory, tested for potency and identity, and given a report that the drug was within the acceptable testing limits. See Tracy Connor, *Georgia Execution of Kelly Gissendaner Postponed for Drug Issue*, Mar. 3, 2015³²; Chris McDaniel, *Georgia Says “Cloudy” Execution Drug Was Just Too Cold, But Expert Gave A Second Possible Reason*, BUZZFEED NEWS (May 11, 2015)³³.
1244. Despite passing the analytical testing that may mirror Defendants' Execution Protocol testing, the compounded pentobarbital precipitated, or developed particles floating in the drug.
1245. The particulate in the compounded pentobarbital would have likely caused an unacceptable pH level in the final product which, in turn, would have caused severe pain upon being injected.

³² Available at <http://www.nbcnews.com/news/us-news/georgia-execution-kelly-gissendaner-postponed-drug-issue-n315651>.

³³ Available at <http://www.buzzfeed.com/chrismcdaniel/georgia-says-cloudy-execution-drug-was-just-too-cold-but-exp#.cpqe8DRX5>.

1246. Being compounded using incorrect compounding techniques or materials have been identified as a possible cause for the precipitation.
1247. Being shipped and/or stored at a temperature that was too low has also been identified as a possible cause for the precipitation.
1248. Nothing in Defendants' Execution Protocol would prevent Defendants from using precipitated drugs in an execution in the same kind of circumstances, as the Gissendaner drugs had "passed" the analytical testing Defendants offer.

Michael Lee Wilson

1249. On January 10, 2014, the State of Oklahoma executed Michael Lee Wilson using what is believed to be IV injection of compounded pentobarbital. *See Graham Lee Brewer, Condemned man's last words lead to questions about lethal injection 'cocktail' in Oklahoma, U.S., The Oklahoman, Feb. 9, 2014.*³⁴
1250. Approximately twenty seconds after being injected with the execution drugs, Wilson stated "I feel my whole body burning." *Id.*

³⁴ Available at <http://newsok.com/condemned-mans-last-words-lead-to-questions-about-lethal-injection-cocktail-in-oklahoma-u.s./article/3932043>.

1251. When pentobarbital is compounded from its raw API form to an injectable liquid, an incorrect compounding procedure will produce inappropriate pH levels which, when injected into the bloodstream, will cause intense burning pain.

Arnold Preito

1252. Recent executions in Texas using what is believed to be compounded pentobarbital have taken significantly longer before death was declared than previous executions using manufactured, FDA-approved pentobarbital.

1253. Texas implemented a one-drug pentobarbital lethal-injection protocol on July 18, 2012, using FDA-approved pentobarbital. Death Penalty Information Center, *State by State Lethal Injection*,
<http://www.deathpenaltyinfo.org/state-lethal-injection>.

1254. Under that protocol, it took 12 minutes until Bobby Hines was declared dead on October 24, 2012. *Texas executes convicted killer for 1991 slaying*, Associated Press, Oct. 24, 2012,
<http://newsok.com/texas-executes-convicted-killer-for-1991-slaying/article/feed/452560>.

1255. But numerous executions have taken significantly longer since Texas began using pentobarbital from a compounding pharmacy in October, 2013. Death Penalty Information Center, *State by State Lethal Injection, supra*.

1256. On January 21, 2015, it took at least 20 minutes before Arnold Prieto was declared dead from a lethal-injection using compounded pentobarbital. Michelle Casady, *Killer of 3 executed, decades after turning down 30-year plea deal*, mysanantonio.com, Jan. 21, 2015.³⁵.

Kent Sprouse

1257. On April 9, 2015, it took at least 22 minutes before Kent Sprouse was declared dead from a lethal-injection using compounded pentobarbital. *Texas Executes Man for Police Officer's 2002 Shooting Death*, Associated Press, Apr. 9, 2015.³⁶

Manuel Garza

1258. On April 15, 2015, it took at least 26 minutes before Manuel Garza was declared dead from a lethal-injection using compounded pentobarbital. Michael Graczyk, *Texas executes San Antonio man for killing police officer*, Associated Press, Apr. 15, 2015, <http://bigstory.ap.org/article/467586558ac3423b86d7c450c9c61882/man-set-be-executed-killing-sanantonio-officer> (last visited Sept. 4, 2015).

³⁵ Available at <http://www.mysantonio.com/news/local/crime/article/Convicted-killer-set-to-die-tonight-turned-down-6030235.php>.

³⁶ Available at http://www.nytimes.com/aponline/2015/04/09/us/ap-us-texas-execution.html?_r=0.

Derrick Charles

1259. On May 12, 2015, it took at least 25 minutes before Derrick Charles was declared dead from a lethal-injection using compounded pentobarbital. Michael Graczyk, *Texas executes Houston man convicted of killing his girlfriend, her mother and her grandfather*, Associated Press, May 12, 2015.³⁷

Gregory Russeau

1260. On June 18, 2015, it took at least 21 minutes before Gregory Russeau was declared dead from a lethal-injection using compounded pentobarbital. *Texas executes man for murdering auto shop owner during crack cocaine binge*, Associated Press, June 18, 2015.³⁸

Jose Villegas

1261. On April 16, 2014, the State of Texas executed Jose Villegas, using what is believed to be compounded pentobarbital.

1262. After the injection started, Villegas is reported to have said “It does kind of burn.” Associated Press, “It does kind of burn,’ Texas inmate

³⁷ Available at <http://globalnews.ca/news/1995091/texas-executes-houston-man-convicted-of-killing-his-girlfriend-her-mother-and-her-grandfather/>.

³⁸ Available at <http://www.dallasnews.com/news/state/headlines/20150618-texas-executes-man-for-murdering-auto-shop-owner-during-crack-cocaine-binge.ece>.

Jose Villegas says as he gets lethal injection for murders of 3,”
Associated Press (April 15, 2014).³⁹

Eric Robert

1263. On or about October 16, 2012, the State of South Dakota executed Eric Robert, using compounded pentobarbital that post-execution analysis revealed was contaminated with fungus.
1264. After the injection started, Robert reportedly “appeared to be clearing his throat and then began gasping heavily. He then snored for about 30 seconds. His eyes remained opened throughout and his skin turned pale, eventually gaining a purplish hue.” Dave Kolpack and Kristi Eaton, “*Eric Robert Execution: South Dakota Executes Inmate Who Killed Prison Guard,*” Associated Press, October 16, 2012.⁴⁰
1265. Robert’s eyes remained open throughout his execution. That fact, according to some experts, is a sign that the compounded execution drugs did not work properly. Stephanie Mencimer, *Does This Secret Drug Cocktail Work To Execute People? Oklahoma Will Find Out Tonight*, MOTHER JONES (April 29, 2014).⁴¹

³⁹Available at

http://www.nola.com/news/index.ssf/2014/04/it_does_kind_of_burn_texas_inm.html.

⁴⁰Available at http://www.huffingtonpost.com/2012/10/16/eric-robert-execution_n_1969640.html.

⁴¹Available at <http://www.motherjones.com/mojo/2014/04/double-execution-tonight-ok-using-secret-experimental-drug-protocol>.

1266. Robert was not declared dead until twenty minutes following injection of the compounded pentobarbital.

1267. This is consistent with being injected with sub-potent pentobarbital.

P. Allegations related to alternative execution methods or manners.

1268. Allegations and arguments related to alternative execution methods or manners will be alleged in the Plaintiffs' Amended Individual Supplemental Complaints to be filed in this case in accordance with the court's scheduling order.

FEDERAL LAW CLAIMS FOR RELIEF AGAINST DRC DEFENDANTS IN THEIR OFFICIAL CAPACITIES AND DRUG SOURCE DEFENDANTS⁴²

First Cause of Action: Eighth and Fourteenth Amendment Violations

1269. The First Cause of Action was previously moved from the Third Amended Omnibus Complaint to be, as applicable, re-alleged in parts or in whole in the various Plaintiffs' Amended Individual Supplemental Complaints. Claims alleging violations of the Eighth

⁴² The claims alleged below are enumerated using the numbering used in the Fourth Amended Complaint filed by Plaintiff Campbell (ECF No. 978). It is intended that the forthcoming Amended Individual Supplemental Complaints filed by individual Plaintiffs will likewise maintain the same numbering. Thus, they are "parallel" in the respect that they use the same numbering and have *some* legal theories and/or factual allegations that are the same. The entirety of the legal theories and the factual allegations, however, is not or will not be necessarily *identical* to the legal theories and/or factual allegations presented in Campbell's Fourth Amended Complaint or the Fourth Amended Complaints filed by Plaintiff Tibbetts and former Plaintiff Otte.

Amendment as incorporated against the states by the Fourteenth Amendment will be alleged in the Plaintiffs' Amended Individual Supplemental Complaints to be filed in this case in accordance with the court's scheduling order.

Second Cause of Action: Fourteenth Amendment Due Process Violations.

1270. As to each of the Due Process Clause violations alleged below, Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Fourth Amended Omnibus Complaint as if fully rewritten here.
1271. An execution carried out using the drugs contemplated in the Execution Protocol will not be "quick," nor will it be "painless," physically and/or mentally.
1272. Defendants are aware that an execution using the Execution Protocol will almost certainly take more than thirty minutes following the injection of the execution drugs until the inmate is dead in accordance with Ohio law set forth in Ohio Revised Code § 2108.40, but they willingly and knowingly disregard this risk.
1273. Defendants are aware than an execution using the Execution Protocol will produce a lingering death as the condemned inmate slowly suffocates to death or suffers a heart attack over a period that is likely to be 10-15 minutes or more, but they willingly and knowingly disregard this risk.

1274. Defendants are aware that an execution using intravenously injected paralytic drug and/or potassium chloride will subject the condemned inmate to searing, unconstitutionally painful burning sensations upon injection if the inmate has not been sufficiently rendered unconscious, unaware and unable to feel and experience pain, and they are aware of the significant risk/certainty that midazolam is incapable of doing just that, but they willingly and knowingly disregard those risks.
1275. Defendants are aware that an execution using improperly compounded drug(s) will subject the condemned inmate to painful burning sensations upon injection intravenously, and they are aware of the significant risk of obtaining improperly compounded drug(s) to use in an execution, but they willingly and knowingly disregard this risk.
1276. Defendants are aware that at least a not-insignificant number of Plaintiffs, including Plaintiff here, possess individual mental/psychological conditions and characteristics which make such them substantially likely to suffer from a paradoxical effect upon injection of the Execution Protocol's drugs, but Defendants willingly and knowingly disregard this risk.
1277. DRC Defendants have created, maintained, and administered an overarching execution policy and written Execution Protocol that, if used to execute Plaintiff's death sentence, will violate his

- constitutionally protected liberty, life, and property interests (as arising from Ohio Rev. Code § 2949.22(A) and DRC Policy 01-COM-11) in expecting and receiving a “quick and painless death” and/or a humane and dignified execution.
1278. Ohio Revised Code § 2949.22(A) creates valid liberty, life, and property interests vested in Plaintiff in *expecting* a “quick and painless” death.
1279. Ohio Revised Code § 2949.22(A) also creates valid liberty, life, and property interests vested in Plaintiff in *receiving* a “quick and painless” death.
1280. DRC Policy 01-COM-11 is binding state law, and creates valid liberty, life, and property interests vested in Plaintiff in *expecting* a humane and dignified death.
1281. DRC Policy 01-COM-11 is binding state law, and creates valid liberty, life, and property interests vested in Plaintiff in *receiving* a humane and dignified death.
1282. These interests are rights vested in a small class of individuals that have a legitimate claim of entitlement to expect and receive a quick, painless, humane and dignified death.
1283. Plaintiff, as a death row inmate, is a member of the only group that is the intended beneficiary of these guarantees.
1284. Under the express terms of § 2949.22(A) and DRC Policy 01-COM-11, Defendants have no discretion in whether to provide a quick, painless,

humane and dignified death to Plaintiff or some kind of death other than a quick, painless, humane and dignified one.

1285. These interests arising under state law are protected as rights under the substantive and procedural elements of the Due Process Clause of the Fourteenth Amendment.
1286. Having granted Plaintiff interests in expecting and receiving a quick, painless, humane and dignified execution, Defendants may not deprive him of those rights in violation of procedural and substantive due process under the Fourteenth Amendment.
1287. Defendants' denial of Plaintiff's rights to expect and receive a quick, painless, humane and dignified death is arbitrary and conscience-shocking.
1288. The pattern of deviations and/or variations from Defendants' execution policy and written Execution Protocol engaged in by many of the actors involved, intentional or otherwise, combined with the amount of discretion that Defendants claim under their overarching execution policy and under the written protocol, along with substantial evidence of incompetence or inability to perform in the execution context, cumulatively point to an unacceptable risk of violating Plaintiff's rights.
1289. DRC Defendants' most recent discretionary, and unconscionable, choice to resurrect an even worse version of the original three-drug method for use in their Execution Protocol, after renouncing that

method in November 2009 and representing that it would never be used again, and after discarding midazolam after three highly publicized botched executions using that drug, is only the latest, and perhaps most egregious, of the many of deviations and/or variations they have made. In making those representations in November 2009, DRC Defendants assured the Court, the Sixth Circuit, the public, and the Plaintiffs that the paralytic drug and potassium chloride would not be used in Ohio executions going forward. They also knowingly rejected any further use of midazolam as an execution drug. Those drugs, in other words, shall no longer be among the drugs authorized by the execution policy, and their use would thus be a violation of Core Element # 2.

1290. Yet now, seven years later, and in order to expeditiously execute at least three of Plaintiffs, DRC Defendants have intentionally deviated from those binding representations, and have rewritten the policy to “authorize” the use of the very drugs DRC Defendants had previously renounced, as more fully alleged earlier throughout this Fourth Amended Omnibus Complaint.
1291. Defendants manifest deliberate indifference towards, or intentional deprivation of, Plaintiff’s statutorily created liberty, life, and property interests in expecting and receiving a quick, painless, humane and dignified death, interests protected as rights by the substantive and

procedural elements of the Fourteenth Amendment's Due Process

Clause in the following ways:

- by what DRC Defendants include and exclude from their overarching execution policy;
- by their procedures and considerations for development of the written Execution Protocol;
- by their discretionary and faulty administration of the execution policy and the Execution Protocol; and
- by their willingness to shade or color the official record to keep secret critical details about an execution and those who acted outside the law to facilitate it.

1292. Matters that DRC Defendants include or exclude from their overarching execution policy include, but are not limited to, the following:

- Defendants' contemplated use of execution drugs they had previously renounced or rejected for good cause
- Defendants' contemplated use of execution drugs manufactured and/or otherwise supplied by the Drug Source Defendants using compounding or illegally imported or otherwise sourced drugs;
- Defendants' intended use of the specific drugs in the Execution Protocol despite their knowledge of the risks those drugs create;
- Defendants' continued refusal to adequately prepare for and provide medical assistance as necessary in the execution context, even with full notice of that necessity.

1293. Plaintiff's statutorily created liberty, life, and property interests in expecting and receiving a quick, painless, humane and dignified death that are protected as rights are separate and distinct from the rights protecting Plaintiff against cruel and unusual punishment as provided in the Eighth Amendment.

1294. In all the foregoing ways, Defendants violate 42 U.S.C. § 1983 and Plaintiff's rights protected by the Fourteenth Amendment to the United States Constitution.

Third Cause of Action: Violations of First, Sixth, Eighth and Fourteenth Amendment Rights of Access to Counsel, Access to Courts, Ability to Petition for Redress of Grievances, Due Process, and Privileges or Immunities of United States Citizenship.

1295. As to each of the constitutional violations alleged below, Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Fourth Amended Omnibus Complaint as if fully rewritten here.

1296. The Third Cause of Action was withdrawn in the Third Amended Omnibus Complaint due to changes that were made in 01-COM-11 that appeared to alleviate the constitutional concerns previously alleged about accessing the courts through counsel to seek redress for grievances and raise matters of constitutional import.

1297. Evidence from the recent execution of Gary Otte on September 13, 2017 using the version of 01-COM-11 adopted Oct. 7, 2016 demonstrates, however, that those changes are insufficient and/or not adhered to in practice.⁴³

⁴³ The Third Cause of Action as previously alleged in the Second Amended Omnibus Complaint primarily involved allegations about the inmate being required to give up a lay witness in order to have an attorney witness his execution, along with allegations regarding the number of an inmate's counsel permitted to witness the execution and, therefore, the lack of having an

1298. Under Defendants' current execution protocol and the speed at which they do and intend to inject the paralytic drug, time is of the essence if matters go awry and there is evidence the inmate is still conscious, aware, and/or sensate, or if there is evidence the inmate is being subjected to severe pain or suffering, whether from the drugs, or from Defendants' efforts to obtain IV access, or any other matter related to the execution.
1299. Even a delay in contacting the courts measured in the seconds will mean the difference between protecting the inmate from suffering severe pain and subjecting the inmate to unconstitutional cruel and unusual punishment in the form of severe pain and suffering.
1300. Defendants' execution policy and written execution protocol provides no mechanism by which Plaintiff can communicate directly with his counsel in the event that Defendants' attempt to execute Plaintiff

attorney able to simultaneously witness the events in the death chamber and call on the phone back to the waiting room. The Third Cause of Action also included allegations about Defendants preventing an inmate from confidentially communicating with his counsel and counsel being prevented from being able to timely assert constitutional claims to the courts and other authorities with power to stop an execution. Modifications made to 01-COM-11 to permit one or two attorneys to witness in addition to the three lay witnesses, as well as lack of any evidence that would demonstrate Defendants would prevent or hinder an attorney from using the Death House phone to call to the waiting areas lead to the Third Claim being withdrawn. That factual landscape has now changed, however, following the Otte execution when Defendants prevented Otte's counsel from quickly accessing the courts.

begins to go awry or to subject Plaintiff to sure or very likely unconstitutional harm, when time is of the essence.

1301. Defendants' execution policy and written execution protocol provides no mechanism by which counsel can communicate directly to those Defendants in the death chamber and/or the equipment room who are responsible for carrying out the execution.
1302. Defendants' execution policy and written execution protocol provides no mechanism by which Plaintiff's counsel can communicate directly with the federal and/or state courts or other governmental officials in the event that Defendants' attempt to execute Plaintiff begins to go awry or to subject Plaintiff to sure or very likely unconstitutional harm, when time is of the essence.
1303. These failures of the protocol, as written or as administered create an environment that will likely suppress the timely assertion of non-frivolous constitutional claims.
1304. Defendants' execution policy and written execution protocol mandates that counsel, at all times after entering the witness room, "shall have free access to the phone near the entrance door of the Death House." 01-COM-11, Oct. 7, 2016, ¶ VI.G.2.
1305. That phone is the only way counsel in the Death House can communicate information out of the Death House.
1306. To relay information out of the Death House, counsel in the witness room must use the phone to call to the "waiting room" area of SOCF,

where another person will be situated “during all times after the death warrant is read.” (*Id.*)

1307. The person in the waiting room is then permitted to call an outside line, such as the courts. (*Id.*)
1308. In practice, this has meant calling the United States District Court for the Southern District of Ohio, but Defendant Governor Kasich is also empowered to halt an execution at any time.
1309. During the execution of Gary Otte, attorney Carol Wright, one of Otte’s appointed counsel who was witnessing the execution on Otte’s behalf, observed evidence that suggested Otte was still conscious, aware, and/or sensate when he began experiencing severe pain and suffering following the injections of midazolam, which began at 10:39:49 a.m. according to the timeline execution log produced by Defendants.
1310. Otte exhibited active tear production—a sign that he was sensate to, and experiencing, severe pain and suffering, not rendered unconscious, unaware and insensate—from the time shortly after Defendants began injecting the midazolam, and that active tear production stopped only after the paralytic drug was injected and took effect.
1311. Even before Defendants entered the Death Chamber to conduct their reflex checks, Attorney Wright attempted to go to the telephone and call to the family waiting room so that counsel in that room could

contact the court seeking a temporary restraining order preventing Defendants from injecting the paralytic or the potassium chloride while Otte was still demonstrating signs he remained conscious, aware, and/or sensate.

1312. For approximately one and a half to two minutes, Defendants or their agents prevented Wright from leaving the witness room to access the telephone on the wall of the Death House.
1313. The door between the witness viewing area and the hallway where in the phone is located was locked, preventing Attorney Wright from leaving the room.
1314. Defendants or their agents provided no justification to Attorney Wright of why she was being prevented from accessing the phone, other than stating that an undefined “they” had instructed that witnesses were not permitted to leave the witness area.
1315. Defendants later provided a statement to the press in response to a question of why Attorney Wright was not permitted to leave the witness room to access the phone in which they claimed that they carried out Otte’s execution in compliance with the execution policy and without complication.
1316. In the same statement, Defendants claimed that they needed to verify Attorney Wright’s identity and her intention.
1317. Defendants’ statement is a post-hoc rationalization with no basis in fact. Attorney Wright’s identity had already been verified before she

was permitted to enter the SOCF facility, and again when she was allowed to leave the family waiting room area and traverse to the Death House. And her intentions of needing to use the telephone—to which the execution protocol provides her “free access”—were clearly stated.

1318. Wright was eventually permitted to leave the witness room to place a call to the family waiting room, at which point Attorney Allen Bohnert immediately telephoned the federal district court at 10:45 a.m.
1319. The midazolam injections were completed at 10:42:13 a.m. according to the execution timeline log that Defendants produced.
1320. Defendants began the paralytic drug injections at 10:43:23 a.m. according to the timeline log.
1321. Thus, the delay caused by Defendants’ preventing Attorney Wright from accessing the phone and, accordingly, preventing Otte’s counsel from contacting the courts, afforded Defendants the opportunity to forge ahead with the paralytic and potassium chloride injections without the court’s intervention and when Otte was still conscious, aware, and/or sensate to the severe pain and suffering he was already experiencing and that he indisputably would experience upon injection of the paralytic drug and potassium chloride.
1322. Court intervention to ensure the paralytic drug was not injected into Mr. Otte while he was still aware, conscious, and/or sensate to the severe, unconstitutional pain from the paralytic was still possible

when Attorney Wright attempted to access the telephone and in the time immediately thereafter.

1323. During the execution of Ronald Phillips, Attorney Trevor Clark, Assistant Chief Legal Counsel for ODRC, expressly assured Phillips's counsel that Magistrate Judge Merz had been provided the direct phone number to be able to call straight to the equipment room to issue an oral order to Defendants if an immediate injunction was sought and needed.
1324. Defendants, by delaying Attorney Wright from accessing the Death House telephone long enough to allow them to start injecting the paralytic drug (only 1 minute and 10 seconds after they concluded the midazolam injections), made it impossible for the court to intervene before Defendants injected the paralytic.
1325. Whereas there was previously no evidence that providing a telephone on the wall of the Death House was insufficient to protect a condemned inmate's rights to access his counsel, the courts and/or his right to petition the applicable authorities to seek redress of his grievances, the Otte execution now provides precisely that evidence.
1326. If and when an execution goes awry, Defendants will prevent Plaintiff from being able to communicate in a timely manner any matter that requires the halting of the execution by law.
1327. By denying or placing conditions or restrictions on Plaintiff's ability to communicate to the courts or others who may be in a position to halt

an unconstitutional execution, Defendants' execution policy and written execution protocol denies or places impermissible conditions or restrictions on Plaintiff's right to confidential communication with his counsel and on counsel's ability to access the courts and therefore Plaintiff will be denied either his right to access counsel, his right to access the courts and/or his right to petition the applicable authorities to seek redress of his grievances.

1328. In all the foregoing ways, Defendants' execution policy and written execution protocol denies Plaintiff's rights protected by the First, Sixth, and Eighth Amendments to the United States Constitution, as well as by the Privileges or Immunities Clause and the Due Process Clause of § 1 of the Fourteenth Amendment to the United States Constitution, including the right: to free speech; to access the courts; to petition the government for redress of his grievances; to be free from cruel and unusual punishment; to the privileges or immunities guaranteed to citizens of the United States including the rights to come to the seat of government by way of counsel to assert any claim he may have upon the government, to free access to the courts of justice, and to petition for redress of his grievances; and to due process.

Fourth Cause of Action: Fourteenth Amendment Equal Protection Violations

1329. As to each of the Equal Protection Clause violations alleged below, Plaintiff incorporates by reference each and every statement and

allegation set forth throughout this Fourth Amended Omnibus Complaint as if fully rewritten here.

1330. Plaintiff has been or will be treated differently from other similarly situated individuals, burdening his fundamental rights as a member of a class of persons subject to execution at Defendants' hands, without a compelling governmental interest, and/or without any rational basis for the difference in treatment as a class of one, irrationally and arbitrarily, in violation of the guarantees of the Equal Protection Clause of the Fourteenth Amendment.
1331. Defendants violate Plaintiff's rights under the Equal Protection Clause of the Fourteenth Amendment to the federal Constitution by their Execution Protocol as written, and by their actions in applying the Execution Protocol and other binding federal and Ohio state laws relevant here.
1332. Equal protection under the law requires "minimal procedural safeguards" such that there is at least some assurance that the rudimentary requirements of equal treatment and fundamental fairness are satisfied.
1333. The Equal Protection Clause's rudimentary requirements are important here, where the United States Supreme Court has clearly emphasized the necessity of procedural safeguards in a state's lethal injection execution policy, especially including the written protocol, to ensure against violations of fundamental rights.

1334. DRC Defendants' execution policy and written execution protocol is facially violative of the Equal Protection Clause, because it codifies disparate treatment of similarly situated individuals, without sufficient justification, and in a way that is arbitrary, irrational, and capricious.
1335. DRC Defendants have shown an ongoing inability to consistently adhere to their execution policies, practices, procedures, and protocols, including the written Execution Protocol, which will result in the disparate treatment of Plaintiff during his execution compared to similarly situated inmates. *See Cooey v. Kasich*, 801 F. Supp. 2d 623, 656 (S.D. Ohio 2011) ("The perplexing if not often shocking departures from the core components of the execution process that are set forth in the written protocol not only offend the Constitution based on irrationality but also disturb fundamental rights that the law bestows on every individual under the Constitution, regardless of the depraved nature of his or her crimes.")
1336. Defendants' execution protocol has five so-called "Core Elements," from which deviation is absolutely impermissible as a violation of constitutional rights protected by the Equal Protection Clause.
1337. Deviation from any other portion of the execution protocol that is not authorized in advance in writing by the Incident Commander is a deviation of Core Element # 5, such that an unauthorized "non-core" deviation is absolutely impermissible as a violation of constitutional

rights protected by the Equal Protection Clause, because it reveals the critical safeguard of the Execution Protocol and its protections as discretionary rather than mandatory.

A. Equal Protection—Fundamental Rights

1338. Plaintiff, individually and as a member of a class of persons subject to a death sentence under Ohio law, has fundamental rights under the Eighth Amendment to be free from cruel and unusual punishment, to not be subject to a torturous, horrifying, lingering, undignified, or spectacular death, and to be provided necessary medical care by Defendants.
1339. Plaintiff, individually and as a member of a class of persons subject to a death sentence under Ohio law, has individual fundamental rights to privacy, to personal dignity, to bodily integrity, to not be the unwilling subject of forced, involuntary human experimentation conducted by Defendants, and other rights that arise under the principles of liberty and/or natural law, and which are protected by the Ninth Amendment.
1340. Plaintiff, individually and as member of a class of persons subject to a death sentence under Ohio law, has fundamental rights to the protections afforded by the substantive and procedural elements of the Due Process Clause of the Fourteenth Amendment, which protect as rights the following:

- Plaintiff's life, liberty and property interests in expecting and receiving a quick and painless execution, created by the State in § 2949.22;
- those rights created by the State in the written Execution Protocol's mandate that "all execution processes shall be performed in a professional, humane, sensitive, and dignified manner";
- Plaintiff's life, liberty and property interests in expecting and receiving a humane, sensitive and dignified execution; and
- Plaintiff's right to due process in the form of notice of how Defendants will attempt to execute him.

1341. Plaintiff, individually and as member of a class of persons subject to a death sentence under Ohio law, has fundamental rights under the Due Process Clause of the Fourteenth Amendment to the liberty and privacy rights one has in the integrity of one's body, as well as to not be the unwilling, non-consenting subject of human experimentation, and to be free from government conduct that is shocking to the conscience.

1342. Plaintiff, individually and as member of a class of persons subject to a death sentence under Ohio law, has a fundamental right under the Privileges or Immunities Clause of the Fourteenth Amendment to not be the unwilling, non-consenting subject of human experimentation.

1343. Plaintiff has fundamental rights to free speech guaranteed by the First Amendment.

1344. Carrying out an execution is not a compelling governmental interest.

1345. Carrying out an execution at all costs is neither a compelling governmental interest nor a legitimate governmental interest.

1. Equal Protection violation based on burdening of Plaintiff's fundamental rights by Defendants' deviations from the Execution Protocol.

1346. Plaintiff is similarly situated to other condemned inmates to whom Defendants will apply their Execution Protocol.
1347. In applying their Execution Protocol, including in their deviations and/or their variations from their execution policy and written Execution Protocol and their deviations from Core Elements of the Execution Protocol as alleged throughout this Fourth Amended Omnibus Complaint, Defendants are violating the Equal Protection Clause's guarantee of equal treatment for similarly situated persons by severely burdening Plaintiff's fundamental rights through increasing the likelihood that Plaintiff will:
- (1) be denied the Eighth Amendment rights to be given necessary medical care while in DRC Defendants' custody, and to be free from surely or very likely suffering serious harm, including severe physical and/or psychological pain, needless suffering, a torturous, lingering, undignified, or spectacular death, and/or an objectively intolerable risk of such harm which Defendants unjustifiably ignore;
 - (2) suffer deprivation of his fundamental rights to privacy, to personal dignity, to bodily integrity, and to not be the unwilling, non-consenting subject of forced, involuntary human experimentation conducted by Defendants, as protected by the Ninth Amendment, the Fourteenth Amendment's Due Process Clause, or the Fourteenth Amendment's Privileges or Immunities Clause, and as demonstrated during the botched executions of Joseph Clark, Christopher Newton, Dennis McGuire, Clayton Lockett, Joseph Wood, and others, along with the failed execution of Romell Broom, and the experimental—but secretive—approach to executions with which Defendants now operate;

- (3) not be free from suffering conscience-shocking, arbitrary and lawless actions by Defendants that increase the harm to which he will be subjected, in violation of the Fourteenth Amendment;
- (4) be forced to suffer expecting and receiving an execution that is something other than quick and painless, be denied the expectation and receipt of an execution that is humane, and be denied the expectation and receipt of an execution that is dignified, protected by the Fourteenth Amendment; or
- (5) be denied the chance to know sufficiently in advance how Defendants will try to kill him, and therefore denied a meaningful opportunity to come into court to challenge that method of execution, as protected by the Fourteenth Amendment
- (6) be denied the fundamental right to Free Speech under the First Amendment, because the Execution Protocol vests in the Warden complete discretion to cut off the inmate's last words based on the Warden's subjective interpretation of those words as offensive or lengthy, but the Execution Protocol contains no standards by which to determine what is too offensive or lengthy.

1348. The individual and/or pattern of deviations and/or variations from DRC Defendants' Execution Policy and written execution protocol exhibited by many of the actors involved, intentionally and/or recklessly, combined with their wholly subjective, discretionary understanding and application of the execution policy and written Execution Protocol, along with substantial evidence of incompetence or inability to perform in the execution context, cumulatively point to an unacceptable risk of violating Plaintiff's rights.

1349. Defendants rely on Incident Command Systems principles to implement their Execution Protocol.

1350. Defendants have applied Incident Command Systems principles at various times in their execution policy as a shield, a purported guarantee against deviations or variations from the written execution protocol.
1351. And at other times Defendants have applied ICS as a sword by arguing that they need not strictly follow ICS since it is not officially incorporated into 01-COM-11.
1352. But by virtue of DRC Policy 310-SEC-14, ICS principles should be incorporated formally into Defendants' administration of 01-COM-11.
1353. Defendants' application of ICS principles has been inconsistent over time and, upon information and belief, is dependent on the subjective discretion of the Warden of SOCF, the Warden of the Institution where Plaintiff is housed, the Director of DRC, and/or others involved in the execution process, and the identities of the individuals who occupy those positions change regularly.
1354. Moreover, the veracity of documents Defendants produce is called into question, based on evidence of falsification of official records and documents and/or misrepresentations following incidents including or similar in significance to administration of 01-COM-11, including the McGuire "investigation" and report, and former Plaintiff Slagle's suicide during the time when he was subject to the Execution Protocol.

1355. Core Element #5 of the 2016 Execution Protocol is no more than a sham. Despite the seemingly mandatory, limiting language of Core Element # 5, the authority to authorize variations/deviations from the written protocol's requirements is, in fact, unfettered, because the Execution Protocol does not limit the sole authority to authorize deviations or variations from the written protocol to just a single person.
1356. Instead, by the terms of 01-COM-11, any of an unidentified number of persons, with unknown experience, qualification and the like may be considered "the Director" at any given time, injecting more discretion into the execution protocol.
1357. DRC Defendants claim that only a single person other than the DRC Director—that is, Defendant Voorhies—would ever be designated as the Director's designee.
1358. But Defendants, given numerous chances to include that critical limit on discretion in their recent series of Execution Protocol amendments, declined to formalize that purported restriction.
1359. Defendants' assurance that one, and only one, other person would ever be designated as the Director's designee bear no indicia of reliability when DRC Defendants have previously discarded sworn representations and positions when abiding by those sworn representations and positions became inconvenient.

1360. DRC Defendants' most recent discretionary, and unconscionable, choice to resurrect an even worse version of the original three-drug method for use in their Execution Protocol, after renouncing that method in November 2009 and representing that it would never be used again, and after discarding midazolam after three highly publicized botched executions using that drug, is only the latest of the many of deviations and/or variations they have made.
1361. In making those representations in November 2009, DRC Defendants assured the Court, the Sixth Circuit, the public, and the Plaintiffs that the paralytic drug and potassium chloride would not be used in Ohio executions going forward. They also knowingly rejected any further use of midazolam as an execution drug. Those drugs, in other words, shall no longer be among the drugs authorized by the execution policy, and their use would thus be a violation of Core Element # 2.
1362. Yet now, seven years later, and in order to expeditiously execute at least three of Plaintiffs, DRC Defendants have intentionally deviated from those binding representations, and have rewritten the Execution Protocol to "authorize" the use of the very drugs DRC Defendants had previously renounced, as more fully alleged throughout this Fourth Amended Omnibus Complaint.
1363. Defendants' actions in aggressively seeking legislation to keep secret a great deal of information about their activities related to the Execution

- Protocol and their application of it will permit Defendants to hide deviations from the Execution Protocol, including violations of state and federal law, rather than affording open and meaningful oversight.
1364. Defendants' actions administering their Execution Policy and written execution protocol show a pattern of intentional, reckless and/or arbitrary deviations and/or variations from the execution policy and/or written Execution Protocol, such that the safeguards allegedly contained in Defendants' execution policy and written Execution Protocol are applied to a particular inmate arbitrarily and disparately. Such deviations and/or variations are arbitrary and irrational, and/or not necessary to achieve a compelling governmental interest.
1365. Upon information and belief, Defendants have also violated federal and/or state law governing drug manufacturing, compounding, and controlled substances through their deviations and/or variations from their execution policy and written Execution Protocol.
1366. Defendants have also deviated from their Execution Protocol when they have violated or violate applicable federal and/or state statutory or regulatory laws discussed herein.
1367. Defendants' actions deny Plaintiff the guarantee that he will receive the full panoply of procedural safeguards in the written Execution Protocol.
1368. Thus, Defendants' pattern of deviations and/or variations from their execution policy and written Execution Protocol—including but not

limited to their deviation from the November 2009 renouncement of the paralytic drug and potassium chloride and their resurrection of using midazolam in the Execution Protocol—results in each condemned inmate being treated differently. Such disparate treatment severely burdens the fundamental rights of the class of persons that includes Plaintiff.

1369. Defendants' disparate treatment of Plaintiff arising from their individual and/or pattern of deviations and/or variations from their execution policy and written Execution Protocol—including but not limited to their deviation from the November 2009 renouncement of the paralytic drug and potassium chloride and their resurrection of using midazolam in the Execution Protocol—is not necessary to achieve any compelling governmental interest, nor is it the least restrictive means to achieve any compelling governmental interests.

1370. Defendants' execution policy and written Execution Protocol, as applied based on Defendants' repeated pattern of deviations/variations from the execution policy and written execution protocol, violate the Equal Protection Clause of the Fourteenth Amendment because they burden the fundamental rights of the group of condemned inmates—which includes Plaintiff—as articulated in the various allegations herein, without being necessary to achieve a compelling governmental interest.

1371. Defendants' execution policy and written Execution Protocol facially violates the Equal Protection Clause because they codify unequal treatment of similarly situated individuals in such a way that it burdens the fundamental rights of the group of condemned inmates—which includes Plaintiff—as articulated in the various allegations herein, without being necessary to achieve a compelling governmental interest.

2. Equal Protection violation based on burdening of Plaintiff's fundamental rights by Defendants' deviations from Ohio's execution statute.

1372. Plaintiff is similarly situated to other condemned inmates to whom Defendants will apply Ohio's execution statute, Ohio Revised Code § 2949.22.

1373. Ohio Revised Code § 2949.22(A) requires that "a death sentence shall be executed by causing the application to the person, upon whom the sentence was imposed, of a lethal injection of a drug or combination of drugs of sufficient dosage to quickly and painlessly cause death. The application of the drug or combination of drugs shall be continued until the person is dead."

1374. Defendants will apply § 2949.22 to Plaintiff disparately, in violation of the Equal Protection Clause's guarantee of equal protection of the laws.

1375. Defendants will intentionally and/or recklessly deviate from § 2949.22, and therefore apply the law disparately without compelling

governmental interest, by failing to ensure that Plaintiff's execution will be quick.

1376. Defendants will intentionally and/or recklessly deviate from § 2949.22, and therefore apply the law disparately without a compelling governmental interest, by failing to ensure that Plaintiff's execution will be painless.
1377. Defendants will intentionally and/or recklessly deviate from § 2949.22, and therefore apply the law disparately without a compelling governmental interest, by failing to continue application of the lethal injection drug(s) until Plaintiff is dead.
1378. Defendants will intentionally and/or recklessly deviate from § 2949.22, and therefore apply the law disparately without a compelling governmental interest, by failing to administer a sufficient dosage of the lethal injection drug(s).
1379. Defendants will intentionally and/or recklessly deviate from § 2949.22, and therefore apply the law disparately without a compelling governmental interest, by using unreliable, illegally sourced drugs, or by using drugs that are inappropriate and incapable of sufficiently protecting Plaintiff from experiencing the horrific pain and suffering of the paralytic and potassium chloride in the revised three-drug method.
1380. Defendants' deviations from § 2949.22's non-discretionary mandates substantially burden the fundamental rights of the class of persons

that includes Plaintiff by increasing the risks identified herein, without being necessary to achieve a compelling state interest.

3. Equal Protection violation based on burdening of Plaintiff's fundamental rights by Defendants' deviations from Ohio's Constitution.

1381. Ohio's state Constitution, Section 9, Article I, prohibits inflicting "cruel and unusual punishments."
1382. Plaintiff is similarly situated to other condemned inmates against whom Defendants will apply Ohio's execution statute, Ohio Revised Code § 2949.22 and the Execution Protocol.
1383. Section 9, Article I of the Ohio Constitution may accord greater civil liberties and protections to individuals and groups than its federal counterpart.
1384. Defendants will apply Section 9, Article I of the Ohio Constitution to Plaintiff disparately, in violation of the Equal Protection Clause's guarantee of equal protection of the laws.
1385. Defendants will intentionally and/or recklessly deviate from the "cruel and unusual punishments" clause of Section 9, Article I of the Ohio Constitution, and therefore apply the law disparately without a compelling governmental interest, by failing to ensure that Plaintiff's execution will not be a cruel and unusual punishment under the state constitution's civil liberties and protections, which are greater than the federal Eighth Amendment.

1386. Defendants' deviations from the "cruel and unusual punishments" clause of Section 9, Article I of the Ohio Constitution substantially burden the fundamental rights of the class of persons that includes Plaintiff by increasing the risks identified herein, without being necessary to achieve a compelling state interest.

4. Equal Protection violation based on burdening of Plaintiff's fundamental rights by Defendants' failing to follow federal and Ohio state laws related to imported drugs, unapproved drugs, misbranded drugs, adulterated drugs, controlled substances, and compounded drugs, including compounding sterile injectable controlled substances to be used as execution drugs.

1387. Plaintiff is similarly situated to others in the general population of persons subject to the federal and Ohio state drug laws identified herein, and/or those persons intended to be protected by those laws, and/or others in DRC Defendants' custody to whom drugs will be administered.

1388. As alleged throughout this Fourth Amended Omnibus Complaint, Defendants violate various federal and Ohio state laws related to imported drugs, unapproved drugs, misbranded drugs, adulterated drugs, controlled substances, and compounded drugs, including compounding sterile injectable controlled substances to be used as execution drugs.

1389. In violating federal and Ohio state laws as alleged herein, Defendants intentionally and/or recklessly treat the class of persons who are the intended beneficiaries of those laws—which includes Plaintiff—

disparately from others similarly situated, namely the general population of persons subject to those laws and/or those persons intended to be protected by those laws, and/or others in DRC Defendants' custody to whom drugs will be administered.

1390. By dramatically reducing the protections to Plaintiff's health from the possibility of harmful, dangerous, painful, adulterated, misbranded, or poorly compounded drugs, including controlled substances, that those laws were created to provide, Defendants' intentional and/or reckless violations of the federal and state drug laws as alleged herein substantially burden the fundamental rights identified herein of the group of persons that includes Plaintiff, without being necessary to achieve a compelling state interest.
1391. Defendants' violations of the federal and state drug laws as alleged herein also intentionally and/or recklessly apply the law unequally to Plaintiff by purporting to permit Drug Source Defendants and DRC Defendants to engage in illegal activity to compound, import, dispense, distribute, administer, transport, transfer, purchase, or otherwise engage in a broad host of activities identified herein related to controlled substances to be used as execution drugs, when such activity would ordinarily subject those Defendants to criminal prosecution in federal and/or state court or civil administrative enforcement sanctions for their actions.

1392. Defendants' tacit endorsement of illegal activity in the name of carrying out an execution at all costs is arbitrary and irrational, and especially when combined with Defendants' strong desire to keep secret their activities related to executions, it substantially burdens the fundamental rights of the group of persons that includes Plaintiff which are identified herein—especially Plaintiff's Due Process Clause right to be free from governmental activity that shocks the conscience, his Eighth Amendment right to be free from cruel and unusual punishment, and his rights against being an unwilling, non-consenting subject of human experimentation—without being necessary to achieve a compelling state interest.

5. Equal Protection violation based on burdening of Plaintiff's fundamental rights by Defendants' deviations from Ohio's definition-of-death law.

1393. Plaintiff is similarly situated to others to whom Ohio's definition-of-death law, Ohio Revised Code § 2108.40, applies.

1394. DRC Defendants will intentionally and/or recklessly apply Ohio statutory law disparately to Plaintiff when they deviate from the statute that defines, for purposes of Ohio law, when death has occurred, by declaring Plaintiff's death following injection of the lethal drugs under the Execution Protocol within the time when the cessation of circulatory and respiratory functions or all functions of the brain, including the brain stem, remains reversible with the appropriate resuscitative care.

1395. By using an Execution Protocol that they know will produce a lingering death of indeterminate duration, Defendants are intentionally and/or recklessly treating Plaintiff and other condemned inmates disparately.
1396. Instead of applying the statute, DRC Defendants and their agents will declare death prematurely at a time to be determined at Defendants' discretion, and then proceed as if Defendant is dead when he will not be.
1397. DRC Defendants' disparate application of Ohio's definition-of-death statute substantially burdens the fundamental rights identified herein of the group of persons that includes Plaintiff, without being necessary to achieve a compelling state interest.

6. Equal Protection violation based on burdening of Plaintiff's fundamental rights by Defendants' deviations from federal and Ohio state laws prohibiting non-consenting human experimentation.

1398. Plaintiff is similarly situated to others to whom federal and Ohio state laws prohibiting non-consenting human experimentation protect, including those who have a fundamental right against being the non-consenting, unwilling subject of human experimentation by virtue of being United States citizens, those who are protected by ODRC Policy 68-MED-11, Protocol Numbers E-1 through E-4, ODRC Policy 06-RES-01, and ODRC Policy 06-RES-02, by virtue of being in ODRC's custody, and those who are protected by the federal and state statutes

and regulations related to new drugs, approved or unapproved drugs, or the Investigational New Drug Application requirements.

1399. Defendants will intentionally and/or recklessly deviate from the federal and Ohio state laws identified herein by engaging in human experimentation on Plaintiff, an unwilling, non-consenting experimental subject, through experimenting with untested and unknown methods of execution in the Execution Protocol, and through Defendants' manufacturing, compounding, dispensing, administration, or other related actions of drugs that are not approved drugs under the law.
1400. Defendants will intentionally and/or recklessly deviate from federal and Ohio state laws by engaging in human experimentation on Plaintiff, an unwilling, non-consenting experimental subject, through application of the Execution Protocol and Defendants' manufacturing, compounding, dispensing, administration, or other related actions of drugs that will be manufactured, compounded, shipped, stored, and subject to other actions without meaningful oversight.
1401. Especially given the statutory efforts to cloak execution matters in secrecy that Defendants aggressively sought, there is no assurance that the drugs to be used for an execution will be the same from execution to execution, making each execution an experiment on an non-consenting, unwilling human subject.

1402. Defendants' disparate application of federal and Ohio state laws prohibiting administering drugs to an unwilling, non-consenting human subject substantially burdens the fundamental rights identified herein of the group of persons that includes Plaintiff—especially the fundamental right against being an unwilling, non-consenting human experimentation subject protected by the Fourteenth Amendment's Due Process Clause, the Ninth Amendment, and the Privileges or Immunities Clause of the Fourteenth Amendment—without being necessary to achieve a compelling state interest.

7. Equal Protection violation based on burdening of Plaintiff's fundamental rights by Defendants' use of an Execution Protocol and policies by which Defendants deny necessary medical and resuscitative care and permit a lingering death.

1403. Plaintiff is similarly situated to others in ODRC's custody for whom the State of Ohio, through ODRC and its employees and agents, are responsible under the Eighth Amendment to provide necessary medical care.

1404. Defendants will intentionally and/or recklessly treat Plaintiff and other condemned inmates disparately as compared to other Ohio inmates in DRC Defendants' custody who require medical care, by failing to provide the necessary medical and resuscitative care to Plaintiff after his sentence has been imposed by virtue of Defendant

Warden declaring him dead, but before he is dead in accordance with Ohio law, Ohio Revised Code § 2108.40.

1405. At the point Defendant Warden declares the condemned inmate dead, the death warrant has been satisfied, but the inmate will still be statutorily and medically alive, and therefore entitled to necessary medical and resuscitative care that Defendants intentionally and/or recklessly deny.
1406. Defendants know or should know that human executions using midazolam have consistently taken significantly longer than executions using barbiturate drugs.
1407. Defendants know or should know that human executions using compounded execution drugs have consistently taken significantly longer than executions using domestically manufactured drugs.
1408. By using an Execution Protocol that they know will produce a lingering death of indeterminate duration and then refusing to provide necessary medical and resuscitative care after they declared death but before Plaintiff is legally and medically dead, Defendants will intentionally and/or recklessly treat Plaintiff and other condemned inmates disparately.
1409. Defendants' disparate application of necessary medical and resuscitative care to Plaintiff will substantially burden the fundamental rights identified herein—especially the fundamental right to receive necessary medical care guaranteed by the Eighth

Amendment—of the group of persons that includes Plaintiff, without being necessary to achieve a compelling state interest.

8. Equal Protection violation based on burdening Plaintiff's fundamental rights by Defendants' use of midazolam and the unavoidable variation inherent in midazolam's efficacy on individual people.

1410. Plaintiff is similarly situated to other condemned inmates to whom Defendants will apply their Execution Protocol.
1411. There is no legitimate state interest in carrying out an unconstitutional execution.
1412. Midazolam is incapable of producing consistent results in different people. The variations inherent in midazolam's efficacy will render Plaintiff's execution so unreliable that it will result in his disparate treatment compared to similarly situated individuals (*i.e.*, others subject to execution in the State of Ohio). This disparate treatment directly and substantially burdens Plaintiff's fundamental rights identified herein and is not narrowly tailored to achieve a compelling state interest.
1413. Midazolam is not reliably effective as a means to block consciousness, awareness and the ability to feel and experience noxious stimuli such as pain at the level of general anesthesia.
1414. Midazolam has different effects on different people, and may reach a saturation point before rendering a person sufficiently unconscious, unaware and insensate to a level that noxious stimuli cannot overcome that state.

1415. Midazolam can cause a paradoxical effect in people with Plaintiff's characteristics and history. A paradoxical effect occurs when a drug does not work as intended. A paradoxical reaction to midazolam would cause an individual to remain hyper-aware as the execution proceeds. As a result of that heightened state of awareness, such an individual would be conscious and experience severe pain and needless suffering as the second and third lethal drugs are injected. It is highly likely, given Plaintiff's history and personal characteristics, that he will experience a paradoxical reaction if injected with midazolam under the Execution Protocol.
1416. These variations, which Defendants have intentionally incorporated into the Execution Protocol through their intentional choice to use midazolam, cannot be controlled or eliminated, and they mean that the use of midazolam to execute Plaintiff will create a substantial, objectively intolerable risk that the drug will differ in efficacy for him as compared to other individuals subject to execution by the Defendants such that he is at a risk of constitutionally impermissible levels of pain from the second and third lethal drugs. This risk of unreliable efficacy substantially burdens Plaintiff's fundamental rights. Further, this burden is not narrowly tailored to achieve a compelling state interest.

9. Equal Protection violation based on burdening Plaintiff's fundamental rights by Defendants' use of compounded execution drugs and the unavoidable variation inherent in compounded drugs.

1417. Plaintiff is similarly situated to other condemned inmates to whom Defendants will apply their Execution Protocol.
1418. The methods that will be used to produce compounded execution drugs, the process of obtaining, storing, testing, and using these drugs, and the actions and decisions involved in carrying out an execution using compounded execution drugs under the Execution Protocol are incapable of producing consistent results. The variations inherent in these processes will render Plaintiff's execution so unreliable that it will result in his disparate treatment compared to similarly situated individuals (*i.e.*, others subject to execution at Defendants' hands).
1419. This disparate treatment directly and substantially burdens Plaintiff's fundamental rights identified herein, and is not narrowly tailored to achieve a compelling state interest.
1420. The risk of variations that produce unreliable results begins with the drugs that Defendants will obtain to execute Plaintiff. As detailed elsewhere in this Fourth Amended Omnibus Complaint, compounded drugs are not manufactured in an FDA-registered facility using current Good Manufacturing Practices, and have no assurance of consistent quality from lot to lot or from container to container. Moreover, the API for compounded drugs that Defendants will use in

an execution that is obtained from unregistered and uninspected sources has no assurance of consistent quality, constitution, or uniformity, and testing drugs after they have been compounded cannot reliably detect such variations. Further, no enforcement mechanism exists to ensure that compounding pharmacies are following any standards required to produce reliably consistent drugs.

1421. In addition, the short shelf life of compounded execution drugs creates a substantial risk that compounded execution drugs will be made under different standards and conditions. As a result, no two batches of execution drugs will be the same and each lethal-injection execution using compounded drugs will be unlike any before or after.
1422. The risk of variations is further increased because reputable pharmacies have been unwilling to provide compounded execution drugs to Defendants, despite a secrecy law that the legislature passed to encourage cooperation from pharmacists. Defendants' difficulty in securing a reputable and reliable source for execution drugs introduces more variability into the content of the drugs and the quality of the processes used to produce them. It creates a substantial risk that compounded execution drugs will be made by ethically compromised Drug Source Defendants under different standards and conditions, meaning no two batches of drugs will be the same and each lethal-injection execution using compounded drugs will be unlike any before or after.

1423. These variations mean that the use of any compounded execution drugs that Defendants will make or use to execute Plaintiff will create a substantial, objectively intolerable risk that the drug will be the wrong identity or pH level, ineffective, sub-potent, contaminated, unsterile, or otherwise adulterated. This risk of unreliable drugs substantially burdens Plaintiff's fundamental rights. Further, this burden is not narrowly tailored to achieve a compelling state interest.
1424. The procedures required to properly transport, store, test, and administer these drugs after Defendants make or obtain them introduce additional risks of variations that will produce inconsistent results. Variations in how multiple people handle the drugs between when they leave the pharmacy and are used in an execution will create a substantial, objectively intolerable risk that they will function differently in Plaintiff's execution than in those executions of others with whom he is similarly situated. This additional risk of unreliability substantially burdens Plaintiff's fundamental rights and is not narrowly tailored to achieve a compelling state interest.
1425. Finally, Defendants' deviations from Ohio Revised Code § 2949.22, their execution policies, and the written Execution Protocol introduce more variability into their lethal-injection system. The inconsistent results due to this variability will constitute disparate treatment of Plaintiff during his execution compared to similarly situated individuals in a manner that substantially burdens Plaintiff's

fundamental rights and is not narrowly tailored to achieve a compelling state interest.

10. Equal Protection violation based on burdening Plaintiff's fundamental rights by Defendants' intentional removal of the drug concentrations from the Execution Protocol which creates a great likelihood that Defendants will inject Plaintiff with lesser or greater than the required amount of execution drugs.

1426. Plaintiff is similarly situated to other condemned inmates to whom Defendants will apply their execution protocol.
1427. Defendants' planned use of the 2016 Execution Protocol severely burdens Plaintiff's right to be free from cruel and unusual punishment because Defendants removed certain safeguards present in past execution protocols.
1428. Every execution protocol since at least January 8, 2004 has included the concentration requirement in its execution drugs. Those protocols include the prior two protocols using pentobarbital or thiopental sodium and the prior protocols using midazolam and hydromorphone.
1429. Defendants' current Execution Protocol removes a prior safeguard that required Defendants to use a certain concentration of the execution drugs. The current Execution Protocol omits any reference to the concentration of the solution from which any of the execution drugs are obtained. (October 7, 2016 Protocol, VI.F.4.b-d.) For example, in the June 29, 2015 Protocol, the Drug Administrator was required to prepare syringes containing five (5) grams of pentobarbital, 100 ml of a 50mg/ml solution. Alternatively, the Drug

Administrator was required to prepare syringes containing five (5) grams of thiopental sodium, 200 ml of a 25 mg/ml solution. Previous execution protocols likewise required specific concentrations for the applicable drugs in those protocols.

1430. This requirement existed because drugs in solutions, like the execution drugs, have various different concentrations and potencies. Potency refers to the amount of drug required to produce an effect. Some drugs produce a powerful effect at minute doses and others need a large dose to have any effect.
1431. Under the current Execution Protocol, if an execution drug is in a very weak solution, a large amount of solution may be required to obtain the desired effect. Injecting a larger amount of solution will take longer or risk blowing out the IV.
1432. If the Drug Administrators measure the amount of drug to be injected based solely on the volume of solution, but the concentration is incorrect, the incorrect amount of the drug will be injected.
1433. If the execution drugs are obtained from a very strong solution requiring much less of the solution to obtain the designated amount of the drug, a very minute amount of solution may be required but Drug Administrators will likely still inject the mandated volume.
1434. It is likely that Drug Administrators will inject a subpotent injection of the first drug, but a superpotent injection of the second or third drug. Thus the alleged effect of the midazolam will wear off or otherwise be

- insufficient to render and maintain the inmate unconscious, unaware and insensate to severe pain before the paralytic is injected if the midazolam is in a weak solution.
1435. The concentration of the lethal injection drug in the required syringes alters the total volume of the lethal injection dose. This in turn affects the rate of delivery (the push rate) used for the IV administration, and makes it substantially likely that Drug Administrators will use too high of a push rate for the execution drugs.
1436. Because it is substantially likely that Drug Administrators will use too high of a push rate for the execution drugs, it is very likely that they will blow out a vein in the IV administration process, or that a significant amount of any midazolam injected will precipitate at the injection point, thus preventing the required amount of midazolam from reaching Plaintiff's brain before he will be injected with the second and third drugs.
1437. This new unfettered discretion to use any concentration of execution drugs means each Plaintiff will be treated differently depending on what solution Defendants are able to obtain. Thus, Defendants will intentionally treat Plaintiff differently than those persons previously executed with execution drugs drawn from a solution containing a certain concentration of drug and a known potency.
1438. Additionally, Plaintiff will be treated differently from those persons subject to the execution following his execution as any solution with

any concentration can be used at the complete discretion of the Defendants. The failure to specify the concentration of execution drugs in the solution results in a risk that Plaintiff may suffer constitutionally impermissible levels of pain. This risk substantially burdens Plaintiff's fundamental rights as identified herein, and this burden is not narrowly tailored to achieve a compelling state interest.

B. Equal Protection—“Class of One” Disparate Treatment

1439. When an inmate does not allege that the government’s actions in disparately carrying out a lethal-injection execution burden a fundamental right or target a suspect class, the inmate is said to proceed on a so-called “class of one” theory and must prove that the government’s actions lacked any rational basis. *See Cooey*, 801 F. Supp. 2d at 653.
1440. To succeed on a “class-of-one” equal protection claim, a plaintiff must allege either disparate treatment from similarly situated individuals and that the government actors had no rational basis for the difference, *Assocs. of Cleveland Fire Fighters v. City of Cleveland, Ohio*, 502 F.3d 545, 549 (6th Cir. 2007), or that the ‘challenged government action was motivated by animus or ill-will,’ *EJS Properties, LLC v. City of Toledo*, 698 F.3d 845, 864 (6th Cir. 2012).” *Paterek v. Vill. of Armada*, No. 14-1894, 2015 U.S. App. LEXIS 15932, *43 (6th Cir. Sept. 8, 2015).

1441. Defendants will intentionally treat Plaintiff differently than similarly situated individuals by their deviations from or failure to follow the relevant law in a manner that is detrimental to Plaintiff by increasing the risk of a burden on his various fundamental rights identified herein.
 1442. Defendants' disparate treatment of Plaintiff is so unrelated to achievement of any combination of legitimate purposes that it must be irrational and arbitrary.
 1443. Trying to carry out an execution under any procedure that might accomplish the task is not a sufficient basis to rationally justify Defendants' disparate treatment of Plaintiff.
 1444. Defendants' actions are pure arbitrariness—they are irrational and arbitrary by definition because they are in contravention of the law, which negatives any conceivable basis that might support Defendants' actions.
- 1. Equal Protection violation based on Defendants' unequal application of the Execution Protocol to Plaintiff as a class of one.**
1445. Plaintiff is a "class of one," similarly situated with any other condemned inmate who has been or will be subjected to Defendants' execution policy and written Execution Protocol.
 1446. Plaintiff has been or will be singled out arbitrarily and irrationally as a "class of one" who will not be afforded equal protection as represented by the procedural safeguards in Defendants' written Execution

Protocol, when such written safeguards are disregarded, ignored, deemed discretionary or advisory only, or otherwise not followed, intentionally and/or otherwise, during administration of the overarching execution policy.

1447. Plaintiff has been or will be treated differently from other similarly situated individuals without any rational basis for the difference in treatment as a class of one, irrationally and arbitrarily, in violation of the guarantees of the Equal Protection Clause of the Fourteenth Amendment.
1448. Defendants' individual and/or pattern of deviations and/or variations from their execution policy and written Execution Protocol arbitrarily and irrationally treat Plaintiff differently from similarly situated inmates.
1449. Defendants have demonstrated a pattern of irrationally and arbitrarily deviating and/or varying from their execution policy and written execution protocol without any legitimate governmental interest. Combined with the nearly limitless discretion vested in certain actors in the execution process, this means that Plaintiff's death sentence will be administered in a manner such that he will be arbitrarily and irrationally treated differently than similarly situated individuals, to his detriment in the form of increased risk of violations of his fundamental rights, therefore violating his rights as a class of one under the Fourteenth Amendment's Equal Protection Clause.

1450. Defendants' disparate treatment of Plaintiff arising from their individual and/or pattern of deviations and/or variations from their execution policy and written execution protocol is arbitrary, irrational, and furthers no legitimate state interests, and/or there is no relationship between the deviations and/or variations and any legitimate state interest.
1451. Defendants' pattern of deviations and/or variations is irrational because it is arbitrary and capricious; it is a pattern of random deviations and/or variations that changes from execution to execution.
1452. Defendants' arbitrary application of their Execution Protocol is all the more detrimental to Plaintiff because open oversight and scrutiny by Plaintiffs, this Court, and the public have been key in exposing significant constitutional violations regarding Defendants' execution processes and protocols. But after Defendants sought, and Defendant Kasich signed, legislation creating Ohio Revised Code § 2949.221–222, there will be virtually no oversight of any actions related to carrying out the Execution Protocol, and Defendants subjectively believe that there will be virtually no oversight of their actions.
1453. Reducing the level of protection against the risk of harms caused by the Execution Protocol is arbitrary and irrational.

1454. Any justifications that Defendants have offered for their deviations and/or variations from the Execution Protocol are without any rational relationship to a particular condemned inmate.
1455. Defendants' justifications for their deviations and/or variations amount to claims of administrative convenience, which is not a legitimate governmental interest.
1456. By arbitrarily and/or inconsistently following, deviating or varying from the procedural safeguards in Defendant's execution policy and written Execution Protocol, and without any justification related to any specific condemned inmate or to any compelling or legitimate governmental interest, Defendants are arbitrarily denying or significantly burdening Plaintiff's fundamental rights as articulated herein.
1457. Defendants' execution policy and written Execution Protocol are considered binding state law, and thus Defendants violate state law when they fail to abide by the explicit mandates of their execution policy and/or written execution protocol.
1458. Upon information and belief, Defendants have also violated federal and/or state law governing drug manufacturing, compounding, and controlled substances through their deviations and/or variations from their execution policy and written Execution Protocol.
1459. Even if otherwise strictly abiding by their execution policy and written Execution Protocol, Defendants have still violated federal and state

- law governing drug manufacturing, compounding, and controlled substances in a way that disparately applies the law to Plaintiff as a class of one, irrationally.
1460. Defendants have arbitrarily and irrationally deviated from their Execution Protocol, including from Core Elements of the Execution Protocol from which deviations are allegedly impermissible, when they have violated or violate applicable federal and/or state statutory or regulatory laws discussed herein, to Plaintiff's detriment.
1461. State actions that are clearly contrary to law are irrational, and therefore Defendants' deviations and/or variations from, and disregard and violations of, binding law in the form of the Execution Protocol and other applicable federal and state statutes and regulations, are irrational.
1462. Condemned inmates subject to Defendants' execution policy and their written Execution Protocol—including Plaintiff—are dissimilar in only immaterial respects as it relates to Defendants' pattern of deviations and/or variations, and/or Defendants' deviations and/or variations are not rationally founded on differences that are real and not illusory.
1463. By arbitrarily and/or inconsistently following, deviating or varying from the procedural safeguards in Defendants' execution policy and written Execution Protocol, Defendants are arbitrarily and intentionally treating Plaintiff differently than other similarly situated

inmates or irrationally singling him out as a class of one without any relation to differences between Plaintiff and otherwise-similarly-situated individuals, to Plaintiff's detriment and contrary to law or otherwise without any rational relationship to a legitimate governmental interest.

1464. Defendants' execution policy and written Execution Protocol facially violates Plaintiff's rights as a class of one under the Equal Protection Clause because they codify arbitrary and irrational unequal treatment of similarly situated individuals, such as Plaintiff, without any legitimate governmental interest and in a manner detrimental to Plaintiff, and Defendants seek to hide this arbitrary and irrational unequal treatment from Plaintiffs, the media, the courts, and the general public.

2. Equal Protection violation based on Defendants' unequal application of Ohio's execution statute to Plaintiff as a class of one.

1465. Plaintiff is a "class of one," similarly situated with any other condemned inmate who has been or will be subjected to Ohio's execution statute, § 2949.22.

1466. Defendants' implementation of Ohio Rev. Code § 2949.22 and the Execution Protocol irrationally, intentionally and/or recklessly treats death-row inmates, including Plaintiff, disparately by arbitrarily subjecting inmates to severely painful, lingering, undignified, or

spectacle executions despite its obligation to consistently provide quick and painless executions.

3. Equal Protection violation based on Defendants' unequal application to Plaintiff, as a class of one, of federal and Ohio state laws related to imported drugs, unapproved drugs, misbranded drugs, adulterated drugs, controlled substances, or compounded drugs, including compounding sterile injectable controlled substances to be used as execution drugs.

1467. Plaintiff is a "class of one," similarly situated with those who are subject to the federal and Ohio state drug law or those who are intended to be protected and kept safe from exposure to harmful drug products by those laws—specifically, those persons who will be exposed to controlled substances, or drug products produced by manufacturers, foreign or domestic, or by compounding pharmacies or outsourcing facilities.

1468. Defendants intentionally and/or recklessly treat Plaintiff as a class of one disparately from others similarly situated.

1469. Defendants' intentional and/or reckless violations of federal and Ohio state drug laws intentionally violate Plaintiff's rights as a class of one, arbitrarily and irrationally, thereby exposing him to significant risks of harm from illegal and illegally sourced drugs and significantly burdening his fundamental rights as identified herein, without any rational relationship to any legitimate state interest, because state actions that are clearly contrary to law are irrational.

1470. Any possible rational or legitimate state interest is “negated” when Defendants’ actions are in violation of the law and are, therefore, arbitrary and capricious by definition.
1471. Defendants substantially burden Plaintiff’s fundamental rights identified herein through their intentional and/or reckless violations of the federal and Ohio state drugs laws as alleged herein, which arbitrarily and irrationally exposes Plaintiff to the risks identified herein, to his detriment. Those violations dramatically reduce the protections to Plaintiff’s health from the possibility of harmful, dangerous, painful, adulterated, misbranded, or poorly compounded drugs, including controlled substances, that those laws were created to provide.
1472. That level of risk to Plaintiff is increased significantly due to the restrictions on oversight in Ohio Revised Code §§ 2949.221–222 that were recently created at Defendants’ behest and signed into law by Defendant Kasich.
1473. Defendants’ violations of the federal and state drug laws as alleged herein also intentionally and/or recklessly apply the law unequally to Plaintiff by purporting to permit Drug Source Defendants and DRC Defendants to engage in illegal activity to compound, import, dispense, distribute, administer, transfer, transport, purchase, or otherwise engage in a broad host of activities identified herein related to controlled substances to be used as execution drugs, when such

activity would ordinarily subject those Defendants to criminal prosecution in federal and/or state court or civil administrative enforcement sanctions for their actions.

1474. Defendants' tacit endorsement of illegal activity in the name of carrying out an execution at all costs is arbitrary and irrational, and especially when combined with Defendants' strong desire to keep secret their activities related to executions, Plaintiff will be detrimentally affected by Defendants' lawless activities, including by substantially burdening his fundamental rights identified herein.

4. Equal Protection violation based on Defendants' unequal application of Ohio's definition-of-death law to Plaintiff as a class of one.

1475. Plaintiff is a "class of one," similarly situated to others to whom Ohio's definition-of-death law, Ohio Revised Code § 2108.40, applies.
1476. DRC Defendants will intentionally and/or recklessly apply Ohio's definition-of-death law to him disparately if they apply it to him at all, to his detriment and irrationally because he will likely still be alive, statutorily and medically, at the time DRC Defendants declare him dead and proceed with steps in the Execution Protocol such as removing him from the execution chamber and loading him into a vehicle to deliver him to the person who is responsible for taking possession of Plaintiff's remains.

1477. The range of times in which DRC Defendants declare death demonstrates an arbitrary and/or irrational application, if at all, of Ohio's definition-of-death law.

5. Equal Protection violation based on Defendants' unequal application of federal and Ohio state laws prohibiting non-consenting human experimentation to Plaintiff as a class of one.

1478. Plaintiff is a "class of one," similarly situated with those who are protected by federal and state laws prohibiting human experimentation on non-consenting, unwilling human subjects.

1479. DRC Defendants will intentionally and/or recklessly treat Plaintiff disparately by subjecting him to human experimentation to which Plaintiff has not and does not consent, as alleged herein, to Plaintiff's detriment.

1480. DRC Defendants' disparate treatment is arbitrary and irrational because it violates applicable federal and state-law prohibitions on non-consenting human experimentation, as alleged herein.

6. Equal Protection violation based on Defendants' disparate denial of necessary medical care and permitting a lingering death.

1481. Plaintiff is a "class of one," similarly situated to others in ODRC's custody for whom the State of Ohio, through ODRC and its employees and agents, are responsible under the Eighth Amendment to provide necessary medical care.

1482. Plaintiff is a “class of one,” similarly situated to others to whom DRC Defendants will administer its Execution Protocol and thereby produce a lingering death.
1483. DRC Defendants will treat him disparately, intentionally and/or recklessly, by failing to provide the necessary medical care and permitting a lingering death instead.
1484. DRC Defendants’ actions are arbitrary and irrational, as DRC Defendants have a duty under the Eighth Amendment to provide necessary medical care to one in their custody, and to prevent subjecting Plaintiff to a lingering death.

7. Equal Protection violation based on Defendants’ use of midazolam and the unavoidable variation inherent in midazolam’s efficacy on individuals, which treats Plaintiff unequally as a class of one.

1485. Plaintiff is a “class of one,” similarly situated with any other condemned inmate who has been or will be subjected to execution in Ohio.
1486. The unavoidable variability inherent in midazolam’s efficacy, set out in this Fourth Amended Omnibus Complaint, also violates the Equal Protection Clause because such deviation results in the disparate treatment of Plaintiff as a “class of one.” Defendants will intentionally treat Plaintiff differently than similarly situated individuals by its use of a drug so imbued with risks of variation that it cannot produce reliable results. Plaintiff will suffer as a result of the unreliable efficacy of midazolam.

1487. Defendants have no rational basis for the irrational and arbitrary difference in their treatment of Plaintiff that stems from using a drug whose effects on individuals are not reliably consistent.
1488. Such disparate treatment constitutes a violation of Plaintiff's rights under the Equal Protection Clause of the Fourteenth Amendment.
- 8. Equal Protection violation based on Defendants' removal of any required concentration of the execution drugs which treats Plaintiff unequally as a class of one.**
1489. Plaintiff is a "class of one," similarly situated with any other condemned inmate who has been or will be subjected to execution in Ohio.
1490. The variations created by Defendants' intentional removal of any required concentration of the execution drugs in the Execution Protocol, set out above, violates the Equal Protection Clause because such variation results in the disparate treatment of Plaintiff as a class of one.
1491. Defendants intentionally treat Plaintiff differently than similarly situated individuals by their unregulated use of any concentration of execution drugs in solutions.
1492. The complete lack of any required concentration of execution drugs in solutions cannot produce reliable results.
1493. Plaintiff will suffer as a result of the lack of a required concentration of execution drugs in solutions.

1494. Defendants have no rational basis for their intentional, irrational and arbitrary difference in their treatment of Plaintiff that stems from using any concentration of execution drugs in solutions.
1495. Such disparate treatment constitutes a violation of Plaintiff's rights under the Equal Protection Clause of the Fourteenth Amendment.

Fifth Cause of Action: Violations of Fundamental Rights Arising Under The Principles Of Liberty and/or Natural Law Which Are Protected By The Ninth Amendment.

1496. As to each of the constitutional violations alleged below, Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Fourth Amended Omnibus Complaint as if fully rewritten here.
1497. Defendants' application of their execution policy and written execution protocol, as demonstrated through previous executions such as Clark, Newton, Biros, Berry, McGuire, and the failed execution of Broom, and as alleged herein, along with the facts alleged herein related to executions of inmates in other states using execution protocols similar or identical to Defendants' protocol and procedures and Defendants' connection to those executions, will violate Plaintiff's fundamental, unenumerated rights arising under the principles of liberty and/or natural law that are secured by the Ninth Amendment.
1498. These rights include rights such as Plaintiff's right to privacy, his right to personal dignity, his right to bodily integrity, his right to not be the unwilling subject of forced, involuntary human

experimentation conducted by Defendants, and others inherent in the concepts of liberty and/or natural law.

1499. These fundamental rights, arising from the concepts of liberty and natural law that guided the Framers' understanding of the Ninth Amendment specifically and the Bill of Rights in general, are deeply rooted in this Nation's history and tradition, and they are implicit in the concept of ordered liberty.
1500. Defendants will violate Plaintiff's fundamental, unenumerated rights in violation of the Ninth Amendment through Defendants' haphazard and faulty administration of their execution policy and written Execution Protocol, including, but not limited to, Defendants' demonstrated inability to consistently obtain IV access quickly and with a minimum number of needle sticks, Defendants' inconsistent application of ICS principles over time, Defendants' demonstrated willingness to discount evidence of significant problems during an execution, Defendants' demonstrated unwillingness to recognize the need for resuscitative medical care and equipment on hand and the corresponding need to accurately assess when an inmate has legally died, and Defendants' insistence to this Court that they have not and will not illegally obtain execution drugs even after evidence is revealed suggesting that they have tried to obtain execution drugs in violation of the law; and Defendants' resurrection of a three-drug method that includes three drugs that DRC Defendants have previously rejected.

1501. Defendants will violate Plaintiff's fundamental, unenumerated rights in violation of the Ninth Amendment through their administration of execution drugs, compounded or otherwise, that will cause vomiting, choking, asphyxiating, suffocating, gasping, seizing, tremors, a heart attack, and other disturbing reactions, resulting in an undignified, spectacle execution, or attempted execution, offensive to an inmate's rights protected by the Ninth Amendment.
1502. Defendants will violate Plaintiff's fundamental, unenumerated rights in violation of the Ninth Amendment through their application of their execution policy's and written Execution Protocol's various tasks in such a way as to result in an undignified, spectacle execution, or attempted execution, offensive to an inmate's rights protected by the Ninth Amendment.
1503. Forcing a non-consenting prisoner to be the unwilling, involuntary subject of pharmaceutical or medical experimentation performed on him by those who hold him in custody has long been prohibited internationally, by the United States in accordance with binding international treaties and under controlling federal drug statutes and regulations, and is even prohibited by DRC Defendants' own departmental policies. See ODRC Policy 68-MED-11, Protocol Number E-4, Pharmacy Distribution and Dispensing Operations, ¶ III.D, Experimental or Investigational Drugs; ODRC Policy 06-RES-01, Research Approval Process, ¶ V ("The participation of offenders

under the jurisdiction of the [ODRC] in medical, pharmaceutical, and/or cosmetic research projects is prohibited unless there is a clear benefit for the inmate given his/her health status."); ODRC Policy 06-RES-02, Human Subjects Research Policy, ¶ VI.A.5.c (stating that investigational or experimental projects "that represent a risk to offenders are not allowed"); ¶ VI.C.1 (stating the "participation of offenders under the jurisdiction of the Department in medical, pharmaceutical, and/or cosmetic projects is prohibited unless there is clear benefit to the individual offender based on his/her need for a specific medical procedure or pharmaceutical that is not generally available. **Participation of offenders** in medical or **pharmaceutical testing purely for experimental** or research purposes **is not permitted.**") (emphasis added); ¶ VI.C.3; ¶ VI.C.6.

1504. Defendants will violate Plaintiff's fundamental, unenumerated rights in violation of the Ninth Amendment through their application to him of experimental or investigational drugs, to which he does not and, indeed cannot, consent, thereby forcing him to become the unwilling, involuntary subject of forced human experimentation in violation of an inmate's rights protected by the Ninth Amendment.
1505. In all the foregoing ways, Defendants violate Plaintiff's fundamental, unenumerated rights in violation of the Ninth Amendment to the United States Constitution and 42 U.S.C. § 1983.

Sixth Cause of Action: First Amendment Free Speech Clause Violations

1506. As to each of the constitutional violations alleged below, Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Fourth Amended Omnibus Complaint as if fully rewritten here.
1507. Defendants' written protocol places restrictions on the length and content of an inmate's last statement, and those restrictions are not necessary or the least restrictive means to achieve a governmental interest.
1508. The restrictions will have a chilling effect on an inmate's expressive speech because the written protocol gives the Warden discretionary but unguided authority to impose restrictions on the length of an inmate's last statement, and to terminate a statement based on content, *i.e.*, to terminate a statement if the Warden subjectively believes it is intentionally offensive to others, without any further explanation on how those restrictions are to be applied.
1509. Plaintiff has a fundamental right protected by the First Amendment, the Ninth Amendment, and the Fourteenth Amendment to the federal constitution to make a final statement free of the restrictions contained in Defendants' written protocol.
1510. The restrictions in Defendants' written protocol related to an inmate's last words violate well-established First Amendment prohibitions on content-based discrimination in regulating speech.

1511. The restrictions in Defendants' written protocol related to an inmate's last words violate well-established First Amendment prohibitions related to the public forum and/or limited public forum doctrines.
1512. The restrictions in the written protocol related to an inmate's last words discriminate against an inmate's expressive speech on the basis of viewpoint, because the Warden may impose restrictions the Warden subjectively believes to be intentionally offensive.
1513. The restrictions in the written protocol related to an inmate's last words are not reasonable in light of the purpose of an execution, and Plaintiff is provided no alternative way to communicate the entirety of his last words if the Warden restricts Plaintiff's speech.
1514. There are no governmental interests to justify the restrictions on an inmate's expressive speech provided in the written protocol.
1515. There are no valid security concerns even in the prison context because the execution is carried out in a part of the prison complex at SOCF in which no other inmates are present or able to hear or see what is occurring.
1516. The written protocol, facially and as applied to him, violates Plaintiff's freedom of speech rights protected by the First, Ninth and Fourteenth Amendments.
1517. Upon information and belief, the restrictions in Defendants' written protocol related to an inmate's last words also violate the terms of a settlement agreement to which some of the original Defendants in

these lethal injection cases, and at least one former Plaintiff in this action, Frederick Treesh, were a party, in *Treesh v. Taft*, No. 99-624, S.D. Ohio.

1518. Upon information and belief, under the terms of the settlement agreement, Defendants' protocol would place no restrictions on the content and/or the duration of an inmate's last statement.
1519. In all the foregoing ways, Defendants violate Plaintiff's rights to free speech protected by the First Amendment to the United States Constitution and 42 U.S.C. § 1983.

Seventh Cause of Action: Fourteenth Amendment Due Process Violation

1520. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Fourth Amended Omnibus Complaint as if fully rewritten here.
1521. DRC Defendants have only confirmed they will use Plan 3 against former Plaintiffs Phillips, Otte, and Tibbetts. They have been silent on the method of execution they plan to use for Plaintiff.
1522. DRC Defendants have failed to definitively inform Plaintiff about which method of execution they intend to apply to him in such a way that Plaintiff can be sure of which execution method Defendants will use on him, whether Plan 1, Plan 2 or Plan 3.

1523. DRC Defendants have not provided Plaintiff with the identification information of any of the Drug Source Defendants from whom they will obtain the execution drugs to be used at the Plaintiff's execution.
1524. Indeed, DRC Defendants were actively involved, in late 2014, in efforts to persuade the Ohio General Assembly to introduce and enact legislation, *i.e.*, HB 663, that would cause the identification information of Drug Source Defendants and others to be: (a) classified as confidential, privileged under law, and not subject to disclosure by any person, state agency, governmental entity, board, or commission or any political subdivision as a public record under section 149.43 of the Ohio Revised Code or otherwise; (b) no longer subject to disclosure by or during any judicial proceeding, inquiry, or process, except as otherwise provided in the new law; and (c) no longer subject to discovery, subpoena, or any other means of legal compulsion for disclosure to any person or entity, except as otherwise provided in the new law.
1525. These efforts resulted in the enactment of HB 663, which became effective March 23, 2015, and the pertinent provisions referenced here are codified at Ohio Revised Code §§ 149.43(A)(1)(cc), 2949.221, and 2949.222.
1526. Under the purported authority of the referenced provisions of HB 663, DRC Defendants have refused to provide Plaintiff with the identification information of any of the Drug Source Defendants from

whom DRC Defendants will obtain the execution drugs to be used at the Plaintiff's execution.

1527. "The fundamental requisite of due process of law is the opportunity to be heard. This right to be heard has little reality or worth unless one is informed that the matter is pending . . ." *Mullane v. Cent. Hanover Bank & Trust Co.*, 339 U.S. 306, 314 (1950) (internal citations omitted).
1528. "The right to be heard before being condemned to suffer grievous loss of any kind . . . is a principle basic to our society." *Joint Anti-Fascist Comm. v. McGrath*, 341 U.S. 123, 168 (1951) (Frankfurter, J., concurring).
1529. The only meaningful time when Plaintiff can challenge the method of his own execution is before he is executed.
1530. "Fundamental fairness, if not due process, requires that the execution protocol that will regulate a prisoner's death be forwarded to him in prompt and timely fashion." *Oken v. Sizer*, 321 F. Supp. 2d 658, 664 (D. Md. 2004), *stay vacated*, 542 U.S. 916 (2004).
1531. The Execution Protocol purports to provide timely notice to an inmate of the manner in which he or she will be executed including the execution drugs to be used, but that assurance is merely illusory.
1532. There is no definitive deadline in the written protocol by which the Warden must inform the inmate of what the Warden has decided, and the Medical Team can make a different determination at any time—

including even the morning of a scheduled execution—without any further notice to the inmate required.

1533. Plaintiff's due process rights are violated when Defendants provide information about their Execution Protocol but then carry out the execution in a manner that differs from those representations.
1534. DRC Defendants fail and refuse to provide critically relevant information concerning the identification information of the Drug Source Defendants and their experience, training, qualifications, credentials, and performance history.
1535. By failing to require and provide adequate notice of exactly which method of execution the Defendants will use, and of the identification information of the Drug Source Defendants, Defendants are depriving Plaintiff of his right to notice and an opportunity to be heard in the form of a constitutional challenge to Defendants' execution method, in violation of the Due Process Clause of the Fourteenth Amendment.
See First Amendment Coal. of Ariz., Inc. v. Ryan, 188 F. Supp. 3d 940 (D. Ariz. May 18, 2016).
1536. Furthermore, because there is no requirement for background checks, credentialing, or anything of the sort related to which Drug Source Defendants with whom the DRC Defendants will work to manufacture execution drug(s), or Drug Source Defendants' drug manufacturing facilities, and because there is no mechanism by which any assessments or quality-control inspections, testing, analysis, or other

similar procedures of any kind are done to ensure strict compliance with all relevant federal and State of Ohio laws and Core Elements ## 1, 2, and 3, Defendants are depriving Plaintiff of his right to notice and an opportunity to be heard, in violation of the Due Process Clause of the Fourteenth Amendment.

1537. Plaintiff will have no meaningful opportunity to challenge the involvement of Drug Source Defendants in a critical aspect of the written execution protocol if he is not informed in advance about the source of the execution drug(s) to be used for his execution, the specific involvement of each and every Drug Source Defendant, and the identification information of such Drug Source Defendants.
1538. Nor will he have a meaningful opportunity to challenge the use of execution drugs manufactured for the sole purpose of killing him which have a substantial, objectively intolerable risk of being something other than the pure, sterile, unadulterated, not-expired/not past their use-by date, not-imported drugs of the proper potency, content, pH level and other relevant characteristics, as required to be used by the 2016 Execution Protocol and Defendants' execution policies.
1539. Defendants' history of their misadventures in carrying out executions and their history of making representations and then renegeing on those representations, coupled with the essentially unlimited discretion the Execution Protocol purports to invest in the DRC

Director, means that Defendants' ad hoc application of its Execution Protocol violates Plaintiff's right to due process.

1540. In all the foregoing ways, Defendants violate Plaintiff's rights to due process protected by the Fourteenth Amendment to the United States Constitution and 42 U.S.C. § 1983.

Eighth Cause of Action: Fourteenth Amendment Due Process Clause Violations For Experimenting On Non-Consenting Prisoners

1541. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Fourth Amended Omnibus Complaint as if fully rewritten here.
1542. The Fourteenth Amendment protects the liberty and privacy right one has in the integrity of one's body. *See Rochin v. California*, 342 U.S. 165, 169 (1952); *Hurtado v. People of California*, 110 U.S. 516, 536 (1884).
1543. “[N]eedlessly severe intrusions of an individual’s body, *even if that individual [is] a felon and stripped of most of his liberty*, [are] impermissible under the Due Process Clause of the Constitution.” *In re Cincinnati Radiation Litig.*, 874 F. Supp. 796, 818 (S.D. Ohio 1995).
1544. Within the basic protections of individual liberty encapsulated in the Fourteenth Amendment are also the principles established in the Nuremberg Code. *Id.* at 819–22.
1545. The Nuremberg Code, developed to create universal standards for carrying out human experimentation, explicitly states that “[t]he

- voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice” *United States of America v. Brandt* (the Medical Case), II Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10, at 181 (1949).
1546. Ohio state administrative law prohibits administration of experimental or investigational drugs to an inmate unless that drug is the only option to treat a medical condition and written approval has been obtained from the DRC Bureau of Medical Services State Medical Director and the DRC Human Subjects Review Committee. See ODRC Policy 68-MED-11, Protocol Number E-4, Pharmacy Distribution and Dispensing Operations, ¶ III.D, Experimental or Investigational Drugs.
1547. Ohio state administrative law also prohibits participation of offenders in medical or pharmaceutical testing purely for experimental purposes. ODRC Policy 06-RES-02, Human Subjects Research Policy, ¶ VI.C.1.
1548. Ohio state administrative law also prohibits investigational or experimental projects “that represent a risk to offenders.” *Id.* at ¶ VI.A.5.c. This prohibition is not limited to projects that are solely “medical” in nature.
1549. Other portions of Ohio administrative law in the form of ODRC policies likewise prohibit Defendants from subjecting Plaintiff to

execution using experimental or investigational drugs without Defendants' having gone through the required, non-discretionary procedures to engage in experimental or investigational processes.

See, e.g., DRC Policy 06-RES-01.

1550. Upon information and belief, no written approval to administer experimental or investigational drugs to an inmate in the context of an execution has ever been sought or obtained from the DRC Bureau of Medical Services State Medical Director and the DRC Human Subjects Review Committee.
1551. The written application for approval to use experimental or investigational drugs must include the justification for use of the drug(s), as well as an informed consent statement signed by the inmate.
1552. Plaintiff has not signed an informed consent statement authorizing Defendants to use investigational or experimental drug(s) on him during a lethal-injection execution, nor is carrying out his death sentence reasonably considered a "medical condition" for which use of experimental or investigational drug(s) might be permissibly considered.
1553. Because of the lack of data, studies, physician expertise, and the variability of human response, every lethal injection that Defendants conduct is a human experiment. *See In re: Ohio Execution Protocol Litig.*, 994 F. Supp. 2d 906, 913 (S.D. Ohio Jan. 13, 2014).

1554. The Sixth Circuit recently held that Defendants are indeed performing “medical” services in carrying out executions, and that “administration of drugs and intravenous fluids” in which Defendants engage is considered “emergency medical services.” *See In re Ohio Execution Protocol Litig.*, No. 17-3800, 2017 WL 3912735, at *4 (6th Cir. Sept. 7, 2017).
1555. It thus follows that the procedures that this Court has already characterized as “experimental” represent medical and pharmaceutical experimentation, even if not in the traditional sense.
1556. The timing of scheduled executions in Ohio, when compared with the use-by date mandated under Ohio law for compounded sterile injectables, means that Defendants—if they will not be using expired drugs/drugs past their use-by date—will typically need to obtain a new order of compounded execution drugs before each execution.
1557. Each execution conducted with a new batch of compounded execution drugs will be an experimental execution, because there is no guarantee that the drugs involved will be identical from execution to execution.
1558. Any compounded execution drugs are also unapproved investigational New Drugs prohibited by the federal FDCA and Ohio state law, and thus experimental by definition.

1559. Any imported execution drugs unapproved investigational New Drugs prohibited by the federal FDCA and Ohio state law, and thus experimental by definition.
1560. Any manufactured drugs that are ordinarily considered “approved” drugs by the federal FDA are “unapproved” for purposes of using those drugs to carry out a human execution.
1561. The experimental nature of each execution that Defendants conduct is amplified exponentially due to the element of variability added by use of compounded execution drugs, and amplified even further because those compounded execution drugs are made by pharmacists or other Drug Source Defendants who are, by definition, ethically compromised by virtue of being willing to violate their professional ethical standards to provide drugs to be used in a human execution, and amplified further still if any of said Drug Source Defendants are permitted to remain anonymous thereby preventing Plaintiff and the Court from reasonable inquiry into and verification of the Drug Source Defendants’ experience, training, qualifications, credentials, performance history, and adherence to the applicable federal and state laws.
1562. Similarly, the experimental nature of each execution that Defendants conduct is amplified exponentially due to the element of variability added by use of imported and/or misbranded execution drugs, and amplified even further because those imported and/or misbranded

drugs were manufactured in facilities that do not comply with U.S. manufacturing standards and exported and imported by persons who are, by definition, ethically compromised by virtue of being willing to use subterfuge and other nefarious methods to smuggle unapproved, misbranded drugs illegally into Defendants' possession, and amplified further still if any of said Drug Source Defendants are permitted to remain anonymous thereby preventing Plaintiff and the Court from reasonable inquiry into and verification of the Drug Source Defendants' experience, training, qualifications, credentials, performance history, and adherence to the applicable federal and state laws.

- 1563. Prisoners cannot give voluntary consent to human experimentation because they lack the free power of choice.
- 1564. Plaintiff is a prisoner unable to exercise the free power of choice.
- 1565. Even if he could give consent, he does not: Plaintiff does not consent to being experimented on like a human guinea pig by Defendants' use of experimental lethal injection execution drugs.
- 1566. Defendants have no clinical basis for believing any drug combination that Defendants use to execute Plaintiff will cause death without surely or very likely subjecting Plaintiff to severe pain and suffering.
- 1567. Defendants have no clinical basis for believing any drug combination that Defendants use to execute Plaintiff will not cause a lingering death.

1568. Defendants have no clinical basis for believing any drug combination that Defendants use to execute Plaintiff will not cause a humiliating, degrading spectacle.
1569. Any execution of the Plaintiff conducted by Defendants under the Execution Protocol will constitute a human experiment without voluntary consent, using unapproved investigational new drugs illegally compounded and dispensed by an ethically compromised pharmacist, or unapproved, misbranded drugs manufactured in substandard facilities and exported and illegally imported by ethically compromised Drug Source Defendants, all in violation of Fourteenth Amendment. *See In re Cincinnati Radiation Litig.*, 874 F. Supp. 796, 818 (S.D. Ohio Jan. 11, 1995).

Ninth Cause of Action: Fourteenth Amendment Privileges or Immunities Clause Violations For Experimenting on Non-Consenting Prisoners.

1570. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Fourth Amended Omnibus Complaint as if fully rewritten here.
1571. Defendants' application of their execution policy and written execution protocol, as demonstrated through previous executions such as Clark, Newton, Biros, Berry, McGuire, and the failed execution of Broom, and as alleged above, along with the facts alleged above related to executions of inmates in other states using execution protocols similar or identical to Defendants' protocol and procedures

- and Defendants' connection to those executions, will violate Plaintiff's fundamental, unenumerated rights protected against infringement by the Privileges or Immunities Clause of the Fourteenth Amendment.
1572. These rights include rights such as Plaintiff's right to not be the unwilling subject of forced, involuntary human experimentation conducted by Defendants, which is a right secured for the citizens of the United States based on citizenship of the United States because it is a right secured by international treaties. *Slaughter-House Cases*, 83 U.S. 36, 80 (1873); *see also McDonald v. City of Chicago*, 561 U.S. 742, 851–855 (2010) (Thomas, J., concurring).
1573. Although the *Slaughter-House Cases* held that the rights in consideration in that case—the right to property in the form of exercise of a trade—were not privileges or immunities of citizens of the United States within the meaning of the Privileges or Immunities Clause of the Fourteenth Amendment, the Court specified some rights that are, indeed, still protected by that clause of the Constitution even under a narrow interpretation of the clause's reach.
1574. Among those rights the *Slaughter-House Cases* majority opinion confirmed were protected by the Privileges or Immunities Clause of the Fourteenth Amendment are rights secured to citizens by treaties with foreign nations.
1575. The right against being subject to involuntary human experimentation is clear, established as it is in numerous international treaties to

which the United States is a party, including the Universal Declaration of Human Rights, G.A. Res. 217A, U.N. Doc A/810, at 71 (1947); the International Covenant on Civil and Political Rights, G.A. Res. 2200A, 21 U.N. GAOR, Supp. (No. 16) 49, 52, U.N. Doc. A/6316 (1966); the Geneva Convention, 6 U.S.T. 3316, T.I.A.S. 3364, 75 U.N.T.S. 135, Aug. 12, 1949; the Declaration on the Protection of all Persons from Being Subjected to Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, G.A. Res. 3452, Annex Art. 1 (Agenda Item 74), 30 U.N.GAOR, Supp. (No. 34) 91, U.N. Doc. A/10408 (1975); and the Nuremberg Code, G.A. Res. 161, U.N. Doc. A/PV55, at 2244 (1946).

1576. Defendants' Execution Protocol constitutes a forced, involuntary human experimentation conducted by Defendants because this Court has explicitly characterized it as such: "There is absolutely no question that Ohio's current [lethal- injection] protocol presents an experiment in lethal injection processes. The science involved, the new mix of drugs employed at doses based on theory but understandably lacking actual application in studies, and the unpredictable nature of human response make today's inquiry at best a contest of probabilities." *In re Ohio Execution Protocol Litig.*, No. 2:11-cv-1016, 2014 WL 130609, at *6 (S.D. Ohio Jan. 13, 2014).
1577. Defendants' Execution Protocol also constitutes a forced, involuntary human experimentation conducted by Defendants because

- Defendants intend to administer pentobarbital, or thiopental sodium, or midazolam followed by a paralytic drug and potassium chloride, to Plaintiff to cause his death. This administration falls outside any of those drugs' marketed, FDA-approved purposes and outside the course of medical practice, and therefore constitutes the use of "New Drugs" under the FDCA. *See* 21 U.S.C. § 321(p).
1578. The FDCA "generally prohibits access to new drugs unless and until they have been approved by the Food and Drug Administration." *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 697 (D.C. Cir. 2007) (en banc) (citing 21 U.S.C. § 355(a)).
1579. Before FDA approval, a new drug may only be used in humans through a clinical investigation. A "clinical investigation" is "any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice." 21 C.F.R. § 312.3(b).
1580. Defendants' Execution Protocol's experimental use of pentobarbital, thiopental sodium, or midazolam followed by a paralytic drug and potassium chloride, to kill inmates constitutes a "clinical investigation"—that is, an experiment.
1581. Plaintiff will be one of the involuntary, unwilling human "subjects" of Defendants' human experimentation as a recipient of the forcible

application to him of the experimental execution drugs. 21 C.F.R. § 312.3(b).

1582. Plaintiff will also be an involuntary, non-consenting human experimentation subject under Ohio's binding administrative law. See ODRC Policy 68-MED-11, Protocol Number E-4, Pharmacy Distribution and Dispensing Operations, ¶ III.D, Experimental or Investigational Drugs; ODRC Policy 06-RES-01, Research Approval Process; ODRC Policy 06-RES-02, Human Subjects Research Policy.
1583. Because Plaintiff will be an involuntary, non-consenting subject of human experimentation based on (1) this Court's characterization of Defendants' Execution Protocol; (2) the federal regulatory scheme for approving investigational or experimental new drugs; and (3) Ohio's regulatory scheme for administering experimental or investigational drugs to inmates in DRC custody, and because Plaintiff's right against being the unwilling subject of forced, involuntary human experimentation is a fundamental right—a privilege or immunity—guaranteed to him by virtue of being a United States citizen though numerous international treaties to which the United States is a party, Defendants' application of the Execution Protocol to him will violate Plaintiff's rights protected by the Privileges or Immunities Clause of the Fourteenth Amendment even under the most restrictive reading of that clause.

Tenth Cause of Action: Ex Post Facto Violation

1584. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Fourth Amended Omnibus Complaint as if fully rewritten here.
1585. Defendants' Execution Protocol, as written and as applied, violates the Ex Post Facto Clause of Article 1, Sections 9 and 10 of the federal Constitution.
1586. Ohio Revised Code § 2949.22 is the provision of Ohio statutory law that establishes lethal injection as the execution method for Ohio death sentences to be carried out.
1587. Lethal injection was first added to the Ohio death penalty statute in the version of § 2949.22 that was enacted on July 2, 1993, effective October 1, 1993.
1588. The version of § 2949.22 that was effective October 1, 1993 contained the following language:

[T]he person's death sentence shall be executed by causing the application to the person of a lethal injection of a drug or combination of drugs of sufficient dosage *to quickly and painlessly cause death* instead of by electrocution as described in division (a) of this section. The application of the drug or combination of drugs shall be continued until the person is dead.

Ohio Rev. Code § 2949.22(B)(1) (version of statute effective Oct. 1, 1993).
1589. The next revision of § 2949.22, enacted on July 7, 1994, effective October 6, 1994, contained the same language quoted above.

1590. On November 21, 2001, the Ohio General Assembly enacted another amendment to § 2949.22, effective the same day. The November 21, 2001 version of § 2949.22 remains the effective version of the statute today.
1591. Section 2949.22(A), like the previously effective versions of Ohio's death penalty statute, requires a death sentence carried out by lethal injection to be administered by "the application to the person . . . of a lethal injection of a drug or combination of drugs of sufficient dosage *to quickly and painlessly cause death.* The application of the drug or combination of drugs shall be continued until the person is dead."
- Ohio Rev. Code, § 2949.22(A) (version effective Nov. 21, 2001)
- (emphasis added).
1592. The first written execution protocol following the addition of lethal-injection to § 2949.22 was issued by the SOCF Warden on or about March 30, 1994.
1593. The March 30, 1994 version of Ohio's lethal-injection written execution protocol stated that the purpose of the execution procedures rule was "to establish a process for carrying out executions that ensures compliance with" the relevant Ohio statutory and administrative law.
1594. All subsequent versions of Ohio's written execution protocol, whether promulgated as a rule or as a DRC policy, have contained the same or

- substantially similar language requiring that executions must be carried out in accordance with Ohio statutory and administrative law.
1595. Plaintiff is subject to the Ohio lethal-injection statute that requires that his death by lethal-injection be carried out “quickly and painlessly.”
1596. Plaintiff is and has always been subject to a written execution policy requiring adherence to Ohio statutory and administrative law.
1597. The DRC Defendants have changed the law by adopting new and greater punishment than that which first applied to Plaintiff.
1598. The 2016 Execution Protocol and previously enacted versions including those effective October 10, 2013, April 28, 2014, January 9, 2015, and June 29, 2015, diverge from the requirements for a lethal-injection execution to which Plaintiff was previously subject.
1599. These versions of 01-COM-11, as written by their inclusion of compounded execution drugs and including a return to a three-drug protocol using midazolam, and as applied, now fail to guarantee that Plaintiff will be executed in a manner that will “quickly and painlessly” cause his death.
1600. Evidence from executions using compounded execution drugs and from using midazolam in an execution (including as the first drug in a three-drug execution method)—including evidence not considered by the Sixth Circuit in *In re Ohio Execution Protocol*, 860 F.3d 881 (6th Cir. 2017) (en banc) such as the evidence that Gary Otte was

producing active tears following the start of the midazolam injections, through the “consciousness check” and ceasing only after the paralytic drug was injected—demonstrates that the method of execution to be imposed on Plaintiff by Defendants will not be quick, nor will it be painless, if it is carried out using compounded execution drugs.

1601. Instead, his execution will produce an agonizing, physically and mentally painful and torturous, lingering, degrading spectacle that will not ensure his death for an extended period of time.
1602. Evidence from executions using midazolam as one of the execution drugs—including evidence not considered by the Sixth Circuit in *In re Ohio Execution Protocol*, 860 F.3d 881 (6th Cir. 2017) (en banc) such as the evidence that Gary Otte was producing active tears following the start of the midazolam injections, through the “consciousness check” and ceasing only after the paralytic drug was injected—demonstrates that a method of execution using midazolam to be imposed on Plaintiff by Defendants will not be quick, nor will it be painless if Plaintiff is subjected to execution using midazolam in any lethal injection method.
1603. As applied in these circumstances and as written, the 2016 Execution Protocol creates, in the form of physical and mental agony, degradation, serious injury, and/or a lingering and spectacle of death, a significant risk of increased punishment as compared to the statute

that first adopted lethal-injection as a manner of execution in Ohio to which Plaintiff was originally subject.

1604. Plaintiff's death will be significantly more than quick and painless, a substantially greater punishment than that imposed by the statute that first adopted lethal-injection as a manner of execution in Ohio to which Plaintiff was originally subject.

1605. Accordingly, the 2016 Execution Protocol is an unconstitutional ex post facto punishment, and thus invalid as written and as applied.

1606. In all the foregoing ways, Defendants violate Plaintiff's rights protected by the Ex Post Facto Clause of Article I, §§ 9 and 10 of the United States Constitution and 42 U.S.C. § 1983.

Eleventh Cause of Action: Bill of Attainders Violation

1607. Plaintiff withdraws his Eleventh Cause of Action.

Twelfth Cause of Action: Eighth Amendment Violation—Deliberately Indifferent and/or Reckless Denial of Resuscitative Health Care After The Execution Is To Be Completed.

1608. This claim alleging violations of the Eighth Amendment as incorporated against the states by the Fourteenth Amendment will be alleged in the Plaintiffs' Amended Individual Supplemental Complaints to be filed in this case in accordance with the court's scheduling order.

Thirteenth Cause of Action: Eighth Amendment Violation—Deliberate Indifference and/or Reckless Disregard Of Serious Medical Needs.

1609. This claim alleging violations of the Eighth Amendment as incorporated against the states by the Fourteenth Amendment will be alleged in the Plaintiffs' Amended Individual Supplemental Complaints to be filed in this case in accordance with the court's scheduling order.

Fourteenth Cause of Action: Fourteenth Amendment Due Process Clause Violation.

1610. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Fourth Amended Omnibus Complaint as if fully rewritten here.

1611. Plaintiff has a substantive due process right to "freedom from government actions that 'shock the conscience.'" *Range v. Douglas*, 763 F.3d 573, 588 (6th Cir. 2014) (quoting *Bell v. Ohio State Univ.*, 351 F.3d 240, 249–50 (6th Cir. 2003)).

1612. Governmental action that is "arbitrary and capricious" is governmental action that is conscience-shocking. *Id.* (citations omitted).

1613. Governmental action that is in violation of state or federal law is the very definition of arbitrary and capricious.

1614. Accordingly, Plaintiff has a substantive right to be free from governmental action that is arbitrary and capricious because, among other things, it violates federal or state law.

1615. Defendants' Execution Protocol, as written and as applied, involves governmental action by Defendants that violates various state and federal laws related to drug products, and human experimentation, as identified throughout this Fourth Amended Omnibus Complaint, in the course of carrying out a punishment for Plaintiff's violation of the law.
1616. Defendants know of the violations of law that their Execution Protocol includes, and Defendants know of the violations of law that they commit or will commit in carrying out that Execution Protocol; for example, they know they will be violating the various federal and state drug laws, and that they will be violating the laws against non-consenting, involuntary human experimentation.
1617. Defendants know about but recklessly disregard and/or are deliberately indifferent to the numerous violations of state and federal law their Execution Protocol requires and that Defendants commit in carrying out an execution under the Execution Protocol.
1618. For instance, Defendants were on constructive notice regarding the prohibition on importing thiopental sodium to be used for a lethal-injection execution since the federal courts in 2012 and again in 2013 ordered FDA to seize and deny entry to the United States to any shipments of thiopental sodium.

1619. Defendants were on actual notice regarding the ban on importing thiopental sodium to be used for a lethal-injection execution for at least a year if not longer before they adopted their Execution Protocol.
1620. Nevertheless, upon information and belief, Defendants recently attempted to facilitate importing thiopental sodium to use for an execution under the Execution Protocol.
1621. Defendants have also been on notice for over a year that their intentions to obtain and use compounded sterile injectable controlled substances as execution drugs under the Execution Protocol are prohibited by various provisions of federal and state law.
1622. Nevertheless, upon information and belief, Defendants have attempted, and continue to attempt, to facilitate compounding pentobarbital or thiopental sodium to use for an execution under the Execution Protocol.
1623. Defendants have also been on notice for over a year that their Execution Protocol continues to constitute a human experimentation on an unwilling, non-consenting prisoner.
1624. Defendants have had ample time to fully consider the potential consequences of their conduct, but they chose to move forward with their current Execution Protocol nevertheless, and their repeated revisions of the Execution Protocol fail to even acknowledge the violations of law.

1625. Defendants are also aware of the facts that suggest a significant risk of harm to Plaintiff created by their use of pentobarbital or thiopental sodium or the three-drug execution method using midazolam, just as they were aware of the facts that suggested a significant risk of harm if they applied their previous execution protocol to Dennis McGuire.
1626. Defendants' use of a sedative drug that has no pain-blocking characteristics and that is, in practice, virtually never used by itself as an anesthetic drug and that is, in practice, never used to prevent the experience of pain or to induce and maintain unconsciousness, unawareness and insensation to severe pain akin to the state of General Anesthesia, as the critical first drug intended to protect an inmate from experiencing the undisputed severe and torturous pain and suffering associated with air hunger and the second and third drugs in Defendants' three-drug execution protocol is truly shocking to the conscience.
1627. Defendants' injection of an indisputably severely painful paralytic drug approximately one minute after completion of the midazolam injections, before the midazolam injected into Plaintiff has had the time to reach peak/max effectiveness, makes it sure or likely that Plaintiff will be conscious, aware, or at least sensate to the severe pain associated with the paralytic drug's administration. Defendants ignore evidence of that, including evidence from the Otte execution

and other executions using midazolam discussed herein, which is truly shocking to the conscience.

1628. Defendants recklessly disregard and/or are deliberately indifferent to these risks by retaining those drugs in their Execution Protocol and intending to use those drugs in an execution of Plaintiff.
1629. Defendants are also aware of the facts that suggest a significant risk of harm to Plaintiff created by their use of compounded execution drugs or the revised three-drug method.
1630. But Defendants recklessly disregard and/or are deliberately indifferent to these risks by retaining those drugs in their Execution Protocol and pursuing those drugs to use in an execution of Plaintiff.
1631. Defendants are also aware of the facts that suggest a significant risk of harm to Plaintiff created by their use of imported execution drugs.
1632. But Defendants recklessly disregard and/or are deliberately indifferent to these risks by retaining those drugs in their Execution Protocol and pursuing those drugs to use in an execution of Plaintiff.
1633. For all of the foregoing reasons, Defendants' actions in recklessly and/or deliberately indifferently engaging in lawless behavior in pursuit of carrying out a punishment for breaking the law, and Defendants' actions in recklessly and/or deliberately indifferently attempting to obtain and use pentobarbital, or thiopental sodium, or midazolam followed by the paralytic drug and potassium chloride, including compounded or imported versions of those drugs, are

arbitrary and capricious, they are shocking to the conscience, in violation of Plaintiff's rights protected by the substantive component of the Due Process Clause of the Fourteenth Amendment.

Fifteenth Cause of Action: Violation of Racketeer Influenced and Corrupt Organizations Act (RICO) alleged against Drug Source Defendants only

1634. Plaintiff's Fifteenth Cause of Action, Violation of Racketeer Influenced and Corrupt Organizations Act (RICO) alleged against Drug Source Defendants only, is merged with his Sixteenth Cause of Action.

STATE LAW CLAIMS FOR RELIEF AGAINST DEFENDANTS

Sixteenth Cause of Action: Ohio Civil RICO claim against Drug Source Defendants

1635. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Fourth Amended Omnibus Complaint as if fully rewritten here.
1636. This cause of action is brought only against Drug Source Defendants, who are real entities and individuals unknown at this time to Plaintiff.

**A. Legal Basis For The Cause Of Action:
The Ohio Corrupt Practices Act**

1637. The Ohio Corrupt Practices Act, Ohio Revised Code § 2923.31 et seq. (OCPA), is similar but broader than its federal counterpart, the Racketeer Influenced and Corrupt Organizations Act (RICO).
1638. Compared to the federal RICO statute, the OCPA punishes a greater range of offenses, imposes stricter liability on defendants (even those

who merely assist in corrupt activity), relaxes standing requirements, and lowers the burden for obtaining injunctive relief.

1639. Ohio Senator Eugene Watts, the OCPA's Senate sponsor, described the Ohio statute as "the toughest and most comprehensive [RICO] Act in the nation" and "state-of-the-art legislation." *State v. Schlosser*, 681 N.E.2d 911, 914 (Ohio 1997) (citing 57 Ohio Report No. 117, Gongwer News Serv. (June 18, 1985)).
1640. The OCPA incorporates most federal RICO predicates, plus it enumerates many additional offenses under state law that also serve as predicates.
1641. For the purposes of this cause of action, Plaintiff relies on the definition of corrupt activity in the OCPA that incorporates federal RICO predicates.
1642. Like its federal counterpart, the OCPA provides a private cause of action to "[a]ny person who is injured or threatened with injury by a violation" of the statute's substantive provisions. Ohio Rev. Code § 2923.34(A).
1643. Unlike federal RICO, however, the OCPA does not limit the type of injury to "business or property."
1644. In fact, the OCPA expressly contemplates personal injury—and death is the ultimate personal injury—as a redressable injury. Ohio Rev. Code § 2923.32(B)(2).

1645. Also unlike federal RICO, the OCPA imposes a type of “strict liability” on persons who are guilty of participating in, “directly or indirectly,” “two or more incidents of corrupt activity . . . that are related to the affairs of the same enterprise.” *State v. Siferd*, 783 N.E.2d 591, 603 (Ohio Ct. App. 2002).
1646. In other words, “[t]he General Assembly has determined that if a defendant has engaged in two or more acts [related to the same enterprise] constituting a predicate offense, *he or she is engaging in a pattern* of corrupt activity and may be found guilty of a RICO violation.” *Id.*⁴⁴ *see also Bradley v. Miller*, 2013 WL 2370886, at *4 (S.D. Ohio May 30, 2013).
1647. Moreover, the OCPA imposes this strict liability on those who merely assist racketeering activity, not just on those who manage or supervise it. *Siferd*, 783 N.E.2d at 603.
1648. The OCPA also lowers the burden for obtaining injunctive relief by allowing the court to “grant injunctive relief without a showing of special or irreparable injury.” Ohio Rev. Code § 2923.34(D).

B. Stacking the Statutes: From OCPA to CSA.

1649. The Ohio Corrupt Practices Act gives a private cause of action and a right to injunctive relief to “[a]ny person who is injured or threatened

⁴⁴ The case law frequently refers to the OCPA as “Ohio RICO,” and a “RICO violation” in this context accordingly means an OCPA violation.

with injury by a violation of section 2923.32 of the Revised Code.”

Ohio Rev. Code § 2923.34.

1650. In turn, § 2923.32 mandates that “[n]o person employed by, or associated with, any enterprise shall conduct or participate in, directly or indirectly, the affairs of the enterprise through a pattern of corrupt activity or the collection of an unlawful debt.”
1651. In the definitions section, § 2923.31(I)(1), the OCPA incorporates into its definition of “corrupt activity” conduct defined as “racketeering activity” under the federal Racketeer Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. § 1961(1)(D).
1652. In turn, federal RICO, 18 U.S.C. § 1961(1)(D), defines “racketeering activity” as “the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substances Act), punishable under any law of the United States.”
1653. Note that Plaintiff is not proceeding under federal RICO; the only reason this statute is mentioned is because the OCPA incorporates the definitions in the federal statute by reference. Nonetheless, this incorporation by reference allows Plaintiff a private cause of action under the OCPA to enjoin violations of the Controlled Substances Act (CSA), 21 U.S.C. § 801 et seq.

1654. Pentobarbital, thiopental sodium, and midazolam are controlled substances under the CSA.
1655. As detailed below, Drug Source Defendants violate the Controlled Substances Act, which serves as predicate acts for federal RICO, and in turn, Ohio Corrupt Practices Act.

C. Violations of CSA by Drug Source Defendants (Federal Predicate Acts)

1. Unlawful Import Predicate

1656. 21 U.S.C. § 959 prohibits procession, manufacture, or distribution of controlled substances, with punishment set forth in 21 U.S.C. § 960, which contemplates an enhanced sentence of not less than 20 years if death results from the use of the imported drug.
1657. Likewise, 21 U.S.C. § 957 prohibits import into the customs territory of the United States from any place outside thereof any controlled substance unless “there is in effect with respect to such person a registration issued by the Attorney General.”
1658. Penalties for violation of this section are also set forth in 21 U.S.C. § 960 and also contemplate enhanced sentence of not less than 20 years if death results from the use of the imported drug.
1659. Finally, any person who attempts or conspires to commit any offense described in either § 957 or § 959 is subject to the same penalties as those prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

1660. Upon information and belief, Drug Source Defendants acting as importers are violating provisions of 21 U.S.C. § 957 by importing controlled substances into the United States without effectively registering with the Attorney General and while not exempt from such registration under the applicable statutory provisions.
1661. Upon information and belief, Drug Source Defendants acting as manufacturers, importers, or distributors of lethal injection drugs for DRC Defendants are violating 21 U.S.C. § 959(a) by manufacturing or distributing a Schedule II controlled substance intending or simply knowing that it will be unlawfully imported into the United States.
1662. Upon information and belief, Drug Source Defendants acting as distributors of lethal injection drugs for DRC Defendants are violating 21 U.S.C. § 959(b) by possessing a controlled substance when boarding an aircraft with intent to distribute these controlled substances to DRC defendants.
1663. Upon information and belief, Drug Source Defendants are violating 21 U.S.C. § 963 by conspiring with DRC Defendants to import or distribute controlled substances into the United States or by actually attempting to import or distribute controlled substances.
1664. Each of these felonious acts of manufacturing, importing, receiving, concealing, buying, selling, or otherwise dealing in a controlled substance constitutes racketeering activity under 18 U.S.C.

§ 1961(1)(D) and corrupt activity under Ohio Rev. Code
§ 2923.31(I)(1).

2. Unlawful Dispensing Predicate

- 1665. Under the Controlled Substances Act (CSA), 21 U.S.C. § 841(a)(1), “it shall be unlawful for any person knowingly or intentionally . . . to manufacture, distribute, or dispense . . . a controlled substance.”
- 1666. Under § 829, however, “practitioner[s]” may dispense Schedule IV substances with a “prescription.” *Id.*, § 829(b).
- 1667. Specifically, a prescription “must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 C.F.R. § 1306.04(a).
- 1668. Penalties for violations of the dispensing statute are set forth in 21 U.S.C. § 841 et seq. Those penalties contemplate enhanced sentences if death results from the use of the drug.
- 1669. Upon information and belief, Drug Source Defendants who are dispensing or compounding the drugs that are controlled substances for use by DRC Defendants—midazolam, pentobarbital, sodium thiopental—are doing so without a valid prescription.
- 1670. This felonious act of dealing in a controlled substance constitutes racketeering activity under 18 U.S.C. § 1961(1)(D) and corrupt activity under Ohio Rev. Code § 2923.31(I)(1).

3. Unlawful Distributing Predicate

1671. Upon information and belief, Drug Source Defendants violate the Controlled Substances Act by distributing a controlled substance without a valid registration.
1672. Under the Controlled Substances Act (CSA), 21 U.S.C. § 841(a)(1), except as authorized by that subchapter, “it shall be unlawful for any person knowingly or intentionally . . . to . . . distribute . . . a controlled substance.”
1673. Under 21 U.S.C. § 802(11), the term “distribute” means “to deliver (other than by administering or dispensing) a controlled substance or a listed chemical.”
1674. Under 21 U.S.C. § 802(10), the term “dispense” means “to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery.”
1675. Under 21 U.S.C. § 802(27), the term “ultimate user” means “a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.”

1676. Upon information and belief, Drug Source Defendants deliver controlled substances to Defendants or other parties who are not ultimate users of the controlled substance.
1677. Because Drug Source Defendants release the controlled substance to those who are not ultimate users, they are distributing a controlled substance.
1678. Distributing a controlled substance requires a special registration with the Drug Enforcement Administration (DEA) issued by the United States Attorney General. 21 U.S.C. § 822(a)(1).
1679. Registered persons are authorized to manufacture, distribute, or dispense controlled substances only “to the extent authorized by their registration and in conformity with the other provisions of this subchapter.” 21 U.S.C. § 822(b).
1680. The statute provides an exception from registration for agents or employees of registered entities “if such agent or employee is acting in the usual course of his business or employment.”
1681. Upon information and belief, Drug Source Defendants lack the registration necessary to distribute controlled substances to Defendants, which is a violation of 21 U.S.C. § 841(a)(1), and constitutes racketeering activity under 18 U.S.C. § 1961(1)(D) and corrupt activity under Ohio Rev. Code § 2923.31(I)(1).

4. Unlawful Manufacturing Predicate

1682. Under 21 U.S.C. 802(15), the term “manufacture” means the “preparation . . . of a drug or other substance . . . , and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice.”
1683. Manufacturing a controlled substance requires a special registration with the Attorney General. 21 U.S.C. § 822(a)(1).
1684. Registered persons are authorized to manufacture, distribute, or dispense controlled substances only “to the extent authorized by their registration and in conformity with the other provisions of this subchapter.” 21 U.S.C. § 822(b).
1685. Upon information and belief, Drug Source Defendants lack the registration necessary to manufacture a controlled substance, which is a violation of 21 U.S.C. § 841(a)(1), and constitutes racketeering activity under 18 U.S.C. § 1961(1)(D) and corrupt activity under Ohio Rev. Code § 2923.31(I)(1).

5. Unlawful Compounding Predicate

1686. Section 503A of the Federal Food, Drug, and Cosmetic Act is codified as 21 U.S.C. § 353a, requires compliance with USP standards for compounded drugs. 21 U.S.C. § 353a(b)(1)(A)(i).
1687. USP Chapter <797> places responsibility on compounding personnel for ensuring that Compounded Sterile Preparations (CSPs) “are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed.” USP on Compounding at 41.
1688. It mandates that “[c]ompounding personnel shall ensure proper storage and security of CSPs prepared by or dispensed from the compounding facility until either their BUDs [beyond-use-dates] are reached or they are administered to patients.” *Id.* at 66.
1689. It also demands that use and storage procedures, whether at compounding facility or in patient-care setting, must “include daily monitoring and documentation of drug storage refrigerators to ensure temperatures between 2° and 8° and the monthly inspection of all drug storage locations by compounding personnel.” *Id.* at 67.
1690. USP Chapter <797> establishes three contamination categories for CSPs assigned primarily according to the potential for microbial contamination, which would subject patients to risk of harm. *Id.* at 42.

1691. All compounded drugs that DRC Defendants intend to use fall into the high-risk category because they are compounded from nonsterile ingredients but must be made sterile before distribution. *Id.* at 44.
1692. USP Chapter <797> also sets special testing and procedural requirements for high-risk CSPs.
1693. Upon information and belief, Drug Source Defendants engaged in compounding and providing compounded drugs to DRC Defendants are violating USP provisions in the following manner:
- a. by failing to follow verification procedures to check compounding accuracy and sterility, including testing for purity and sterility;
 - b. by failing to conduct and disclose the results of all testing required by USP Chapter 797 for high-risk CSPs;
 - c. by failing to follow and comply with all USP Chapter 797 provisions for high-risk CSPs;
 - d. by failing to ensure proper storage and security of CSPs prepared by them for DRC Defendants until their BUDs are reached or they are administered;
 - e. by failing to ensure that sterility, purity, and stability of CSPs is maintained during packaging, handling, and transport to DRC Defendants;
 - f. by failing to ensure that DRC Defendants implement appropriate operating procedures for storing and administering CSPs;
 - g. by failing to ensure that DRC Defendants implement and follow procedures specific to high-risk CSPs to comply with requirements of USP Chapter <797>;
 - h. by failing to ascertain that DRC Defendants are able to store the CSPs properly, including the use of a properly functioning refrigerator and freezer if CSPs are labeled for such storage;

- i. by failing to conduct daily monitoring and documentation and monthly inspection of locations where DRC Defendants are storing the compounded drugs and to guarantee that the CSPs are stored in proper conditions even at DRC facilities;
- j. by failing to demand that outdated and unused CSPs be returned to the compounding facility for disposition;
- k. by failing to provide appropriate education, training, and supervision to DRC defendants;
- l. by failing to ensure that DRC Defendants use single-dose CSPs within 1 hour after initial needle puncture of the container and discard the rest;

1694. Knowing violations of USP standards related to a controlled substance constitute racketeering activity under 18 U.S.C. § 1961(1)(D), and also constitute corrupt activity within the meaning of Ohio Revised Code § 2923.31(I).

6. Other Predicates

1695. Plaintiff alleges other predicates based on violations of federal and state laws as described elsewhere in this Fourth Amended Omnibus Complaint, including violations of the federal FDCA, the federal CSA, the Ohio Pure Food and Drug Act, the Ohio Controlled Substances Act, the Ohio Pharmacy Practice Act, and others. Plaintiff reserves the right to add additional predicate acts upon further discovery.

D. Violations of Ohio Corrupt Practices Act Based On Federal Law Predicates

1696. As alleged above in the federal predicates, Drug Source Defendants violate the Controlled Substances Act and therefore, are engaged in conduct defined as racketeering activity under 18 U.S.C. § 1961(1)(D).

1697. Engaging in, attempting to engage in, conspiring to engage in, or soliciting, coercing, or intimidating another person to engage in this conduct also constitutes corrupt activity within the meaning of Ohio Revised Code § 2923.31(I).

E. State-law Predicate Acts (Counterfeit Drugs)

1698. In addition to incorporating federal RICO, Ohio Rev. Code § 2923.31(I)(2)(c) also defines corrupt activity as “engaging in, attempting to engage in, conspiring to engage in, or soliciting, coercing, or intimidating another person to engage in” conduct in violation of O.R.C. § 2925.37.
1699. In turn, Ohio Revised Code § 2925.37 prohibits knowingly possessing, making, selling, offering to sell, or delivering “any substance that the person knows is a counterfeit controlled substance.”
1700. As used in Chapter 2925, “Counterfeit controlled substance” means “Any drug that bears, or whose container or label bears, a trademark, trade name, or other identifying mark used without authorization of the owner of rights to that trademark, trade name, or identifying mark.” Ohio Rev. Code § 2925.01(O)(1).
1701. As used in Chapter 2925, “drug” has “the same meaning[] as in section 4729.01 of the Revised Code.” Ohio Rev. Code § 2925.01(C).
1702. In turn, Chapter 4729.01 defines “drug” as including, but not limited to “Any article recognized in the United States pharmacopoeia and national formulary, or any supplement to them, intended for use in

the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals.” Ohio Rev. Code § 4729.01(E).

1703. All drugs listed in the execution protocol are recognized in the United States Pharmacopeia (USP) and the National Formulary (NF).
1704. Manufacturers of sodium thiopental, pentobarbital, midazolam, rocuronium bromide, pancuronium bromide, vecuronium bromide, and potassium chloride have put restrictions on distribution of these drugs.
1705. Specifically, manufacturers limit the sale of these products to a select group of wholesalers, distributors, and direct purchasers under the condition that they will not resell these products to correctional institutions for use in lethal injections.
1706. Government purchasing entities must certify that products they purchase or otherwise acquire are used only for medically prescribed patient care and not for any penal purposes.
1707. Manufacturers further require that these Government purchasers certify that the product is for “own use” and will not resell or otherwise provide the restricted products to any other party.
1708. Upon information and belief, Drug Source Defendants are violating manufacturers’ restrictions on distribution and resale of drugs for use in lethal injection.
1709. Since these drugs bear the manufacturers’ trademarks or other identifying marks, used without authorization, these drugs are

counterfeit controlled substances within the meaning of Ohio Revised Code § 2925.01(O)(1).

1710. Therefore, Drug Source Defendants are knowingly possessing, making, selling, offering to sell, and delivering counterfeit controlled substance within the meaning of Ohio Revised Code § 2925.37. They are thus involved in corrupt activity within the meaning of Ohio Revised Code § 2923.31(I)(2)(c).

F. Corrupt Activities Allegations

1711. Under Ohio Revised Code § 2923.31(C), “enterprise” includes “any individual, sole proprietorship, partnership, limited partnership, corporation, trust, union, government agency, or other legal entity, or any organization, association, or group of persons associated in fact although not a legal entity.”

1712. The same statute defines “enterprise” to include illicit as well as licit enterprises.

1713. Upon information and belief, Drug Source Defendants, Defendants, and others are part of the same enterprise associated in fact. They all are conducting and participating in affairs of an enterprise, in violation of Ohio Revised Code § 2923.32(A)(1).

1714. In the alternative, each Drug Source Defendant is an enterprise, acting for its own pecuniary benefit.

1715. Those Drug Source Defendants who are not individuals are business entities employing or associating with John Doe Defendants, and are enterprises within the meaning of Ohio Revised Code § 2923.31(C).
1716. John Doe Defendants are knowingly conducting or participating in the affairs of these enterprises through a pattern of corrupt activity in violation of Ohio Revised Code § 2923.32(A)(1).
1717. Drug Source Defendants receive pecuniary value for their illegal services.
1718. Drug Source Defendants are knowingly receiving and using or investing proceeds from a pattern of corrupt activity as described above, in violation of Ohio Revised Code § 2923.32(A)(3).
1719. Drug Source Defendants engaging in the pattern of corrupt activity is likely to result in Plaintiffs' deaths.
1720. Plaintiff thus brings this action under Ohio Revised Code § 2923.34(A) as an individual threatened with injury by a violation of § 2923.32 of the Ohio Revised Code.

G. Prayer For Relief for OCPA Claims

1721. Plaintiff asks that the Court enter a judgment on this cause of action in his favor, and for temporary and permanent injunctive relief as necessary.
1722. Plaintiff asks that the Court declare that predicate acts enumerated above, such as manufacturing, delivering, dispensing, or administering controlled substances to the inmates during an

execution without a valid prescription or registration, violate the Ohio Corrupt Practices Act.

1723. Plaintiff asks that under Ohio Revised Code § 2923.34(A)(2) the Court impose reasonable restrictions upon the future activities of Drug Source Defendants, including restrictions that prohibit them from engaging in corrupt activities.
1724. Plaintiff also asks the Court to grant injunctive relief pursuant to the authority of Ohio Revised Code § 2923.34(D), which provides for injunctive relief “without a showing of special or irreparable injury.”
1725. For other relief, including damages and attorneys’ fees, that are available by statute and that the Court may find just.

Seventeenth Cause of Action: Claims for Declaratory Judgment Under Ohio Law Against All Defendants, and for Injunctive Relief Under Ohio Law Against Drug Source Defendants For Violations of Ohio Law.

1726. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Fourth Amended Omnibus Complaint as if fully rewritten here.

A. Rights of Civil Action Under Ohio Law

1727. Under Ohio law, anyone subject to and injured by the criminal acts or activities of another has a right of a civil action against such person, including in respect to any, one or more of the Ohio crimes set forth in this Complaint. See Ohio Rev. Code § 2307.60.
1728. Under Ohio law, a person has a right of civil action under the state corrupt activities statute, Ohio Revised Code § 2923.34(A).

1729. Under Ohio law, a person has a right of a civil action in tort for negligence against a pharmacist or pharmacy that rises to negligence per se if that person shows damages, proximate cause and that the pharmacist or pharmacy violated any provision of the Ohio Pure Food and Drug Act, Ohio Revised Code § 3715 *et. seq.* See *Taugher v. Ling*, 127 Ohio St. 142, 146, syllabus paragraph 3 (1933) (holding that “[t]he Pure Food and Drug Laws of Ohio are statutes passed for the protection of the public, and a violation of them is negligence *per se.*”); *Donley v. Pinnacle Foods Group, LLC*, No. 2:09-cv-540, 2010 U.S. Dist. LEXIS 25144, *3–4, 7–9 (S.D. Ohio Mar. 17, 2010).
1730. Ohio law permits Courts of Record to issue a Declaratory Judgment to declare rights, status and other legal relations, whether or not further relief is or could be claimed. See Ohio Rev. Code § 2721.02(A). No action or proceeding is open to objection on the ground that a declaratory judgment or decree is prayed for under this chapter. *Id.* The declaration may be either affirmative or negative in form and effect. *Id.* The declaration has the effect of a final judgment or decree. *Id.*
1731. Ohio law enables Courts of Record to issue temporary orders restraining an act when it appears a person is entitled to the relief demanded, and such relief, or any part of it, consists in restraining the commission or continuance of such act, the commission or continuance of which, during the litigation, would produce great or

irreparable injury to the plaintiff, or when, during the litigation, it appears that the defendant is doing, threatens or is about to do, or is procuring or permitting to be done, such act in violation of the person's rights respecting the subject of the action, and tending to render the judgment ineffectual. *See* Ohio Rev. Code § 2727.02.

B. Defendants' Violations of Ohio Laws

1732. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Fourth Amended Omnibus Complaint as if fully rewritten here.
1733. Upon information and belief, Defendants would seek, manufacture, procure, acquire, produce, export, import, compound, supply, dispense, distribute, administer, provide, sell, deliver, offer for sale, hold for sale, and/or give away, or otherwise source drugs to carry out a human execution by lethal injection.
1734. By disregarding the FDA, the federal CSA, the federal FDCA, the Ohio Pure Food and Drug Act, the Ohio Controlled Substances Act, the Ohio Pharmacy Practice Act, and the various other Ohio statutory and regulatory provisions cited herein, Defendants have not just undertaken a course and conduct for violating federal law; Defendants have committed and are in continued process of committing crimes under the laws of the State of Ohio.
1735. Defendants or some number of them have undertaken a course and pattern and practice of conduct to engage in the violations of Ohio law

identified elsewhere in this Complaint, as well as the following violations of Ohio law.

Violations Related to Controlled Substances

1736. For purposes of Chapter 2925, “controlled substance” has “the same meaning as in section 3719.01 of the Revised Code.” Ohio Rev. Code § 2925.01(A). In turn, Ohio Revised Code § 3719.01(C) defines “controlled substance” as “a drug, compound, mixture, preparation, or substance included in schedule I, II, III, IV, or V.”
1737. Therefore, sodium thiopental, pentobarbital, and midazolam, whether manufactured or compounded, are controlled substances within the meaning of Chapter 2925.
1738. Upon information and belief, Defendants Drug Administrators, none of whom qualify for the exception in § 2925.11(B)(1), will imminently violate Ohio Revised Code § 2925.11(A) by obtaining, possessing, or using a controlled substance.
1739. Upon information and belief, Defendants Execution Team Members, none of whom qualify for the exception in § 2925.11(B)(1), will imminently violate Ohio Revised Code § 2925.11(A) by using on Plaintiff a controlled substance without a lawful prescription issued by a licensed health professional authorized to prescribe drugs.
1740. Upon information and belief, Defendants Execution Team Members, none of whom qualify for the exception in § 2925.02(B), will imminently violate Ohio Revised Code § 2925.02(A)(1) by using force,

threat or deception to administer a controlled substance to Plaintiff, who will be strapped to a table and forcibly injected with the execution drug(s).

1741. Upon information and belief, Defendants Execution Team Members, none of whom qualify for the exception in § 2925.02(B), will imminently violate Ohio Revised Code § 2925.02(A)(3) by administering a controlled substance to Plaintiff and thereby cause him serious physical harm, including death.
1742. Upon information and belief, other Defendants who do not qualify for the exception in § 2925.02(B), will imminently violate Ohio Revised Code § 2925.02(A)(3) by furnishing a controlled substance to be administered to Plaintiff and thereby cause him serious physical harm, including death.
1743. Upon information and belief, Defendants Execution Team Members will imminently violate Ohio Revised Code § 2925.02(A)(2) by administering a controlled substance with the purpose to cause serious physical harm, including death, to Plaintiff.
1744. Upon information and belief, other Defendants will imminently violate Ohio Revised Code § 2925.02(A)(2) by furnishing, with the purpose to cause serious physical harm, including death, a controlled substance to be administered to Plaintiff.

Violations Related to Dangerous Drugs

1745. For purposes of Chapter 2925, “dangerous drugs” has “the same meaning[] as in section 4729.01 of the Revised Code.” Ohio Rev. Code § 2925.01(C). Thus, under Ohio law, all lethal injection drugs listed in the 2016 Execution Protocol are defined as “dangerous drugs,” because they either require a prescription or are intended for intravenous injection. Ohio Rev. Code § 4729.01(F).
1746. Upon information and belief, Defendants or some number of them have violated or will imminently violate Ohio Revised Code § 2925.22(A), by illegally procuring the administration of, or the “prescription” of, or the dispensing of, dangerous drugs by deception, including, but not limited to, submitting false information in pursuit of a DEA license to import drugs; providing false or misleading paperwork to attempt to import drugs into the United States; using a court order for execution to obtain or compound execution drugs rather than the required prescription that is valid under federal and state law.

Violations Related to Harmful Intoxicants

1747. Ohio Revised Code § 2925.01(I) defines “harmful intoxicant” as “Any compound, mixture, preparation, or substance the gas, fumes, or vapor of which when inhaled can induce intoxication, excitement, giddiness, irrational behavior, depression, stupefaction, paralysis, unconsciousness, asphyxiation, or other harmful physiological effects.”
1748. Lethal injection drugs listed in the 2016 Execution Protocol are harmful intoxicants within the meaning of Chapter 2925.
1749. Upon information and belief, Defendants will imminently violate Ohio Revised Code § 2925.31(A), by obtaining, possessing or using on Plaintiff a harmful intoxicant—lethal injection drugs—with the purpose to induce in Plaintiff intoxication or similar physiological effects, other than for lawful research, clinical, medical, dental, or veterinary purposes.
1750. Upon information and belief, Defendants will imminently violate Ohio Revised Code § 2925.32(A)(1) by knowingly dispensing or distributing a harmful intoxicant to Plaintiff, who is over age 18, when Defendants know or have reason to believe that the pentobarbital or thiopental sodium will be used for the purpose of inducing in Plaintiff intoxication or similar physiological effects.

Violations Related to Pure Food and Drug Laws

1751. Upon information and belief, Defendants will imminently violate Ohio Revised Code § 3715.65(A), by selling, delivering, offering for sale, holding for sale, or giving away a New Drug with respect to which there is no Investigational New Drug Application on file with FDA as required by 21 U.S.C. § 355 and which will be administered to Plaintiff to cause his death.
1752. Upon information and belief, Defendants will imminently violate Ohio Revised Code § 3715.52(A)(1), by engaging in Prohibited Acts defined in that section, specifically: selling, delivering, offering for sale, holding for sale, or giving away lethal injection drugs that are adulterated or misbranded.
1753. Upon information and belief, Defendants will imminently violate Ohio Revised Code § 3715.52(A)(2), by engaging in Prohibited Acts defined in that section, specifically: adulterating or misbranding lethal injection drugs.
1754. Upon information and belief, Drug Supplier Defendants will imminently violate Ohio Revised Code § 3715.52(A)(3), by engaging in Prohibited Acts defined in that section, specifically: delivering or proffering delivery, for pay or otherwise, of adulterated or misbranded lethal injection drugs.
1755. Upon information and belief, DRC Defendants will imminently violate Ohio Revised Code § 3715.52(A)(3), by engaging in Prohibited Acts

defined in that section, specifically: by receiving in commerce drugs that are adulterated or misbranded.

1756. Upon information and belief, Defendants Pharmacies #1-100 and Defendants Pharmacists # 1-100 are or will imminently engage in actions that amount to negligence per se because they are violating provisions of the Ohio Pure Food and Drug Act as identified herein to supply DRC Defendants with compounded drugs that will be administered to Plaintiff and which may or will eventually kill him as a proximate result of being injected with those compounded drugs.

Other Violations

1757. Upon information and belief, Defendants or any of them have discussed, corresponded about, agreed, whether informally or formally or in principal or in contact, whether currently or for a future agreement, and contingently or otherwise, and taken steps to procure, manufacture, produce, export, import, compound, supply, distribute, provide, sell, deliver, offer for sale, hold for sale, or give away or otherwise source the drugs to be used to carry out a human execution under the Execution Protocol.
1758. Upon information and belief, DRC Defendants have or will imminently negligently fail to prevent or halt the commission of the crimes under Ohio law identified herein, in violation of Ohio Revised Code § 2921.44.

1759. Upon information and belief, DRC Defendants have or will imminently negligently fail to perform their lawful duties to carry out a quick and painless execution of Plaintiff, in violation of Ohio Revised Code § 2921.44.
1760. Upon information and belief, DRC Defendants have or will imminently recklessly fail to perform the duties expressly imposed by law with respect to their public servant's offices, such as duties related to carrying out Plaintiff's quick and painless lethal-injection execution in strict compliance with the Execution Protocol and all applicable federal and state policies, administrative regulations and statutes as identified herein. DRC Defendants know about, but recklessly disregard, the allegations of illegal activity alleged herein.
1761. Upon information and belief, Defendants have or will imminently perform acts with respect to carrying out a lethal-injection execution under the Execution Protocol that are expressly forbidden by law, as alleged herein.
1762. The FDA made it clear to Defendants, including Drug Source Defendants through DRC Defendants, that Defendants were without legal authority to issue or take action in reliance upon any instrument to engage in transactions for or relating to the importation of thiopental sodium into the United States.
1763. Drug Source Defendants have been on notice, constructive or actual, that Defendants were without legal authority to issue or take action in

reliance upon any instrument to engage in transactions for or relating to the compounding of pentobarbital or thiopental sodium to use for an execution.

1764. Defendants—including Drug Source Defendants—have criminally and unlawfully cast aside the Ohio Revised Code’s requirements and prohibitions identified herein. By doing so, Drug Source Defendants have undertaken to commit against Plaintiff various crimes identified and prohibited by Ohio law. *See* Ohio Rev. Code § 2921.52(B)(3)–(4).
1765. Pursuant to Ohio Revised Code § 2921.45, Defendants, under color of their office, employment, or authority, have undertaken to knowingly deprive, or conspire or attempt to deprive Plaintiff of a constitutional or statutory right, as alleged herein.

C. Relief

1766. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Fourth Amended Omnibus Complaint as if fully rewritten here.
1767. Pursuant to Ohio Revised Code § 2307.60, Plaintiff has the right to a civil action to recover from and against Defendants the full costs, attorney’s fees and damages, including, but not limited, to punitive damages, in respect to such actions of Defendants that are offenses against Plaintiff that are of a criminal nature.
1768. Pursuant to Ohio law, Plaintiff has a right to a civil action under the state RICO statute.

1769. Pursuant to Ohio law, Plaintiff has the right to a civil action in tort for negligence to recover from and against Defendants Pharmacies # 1–100 and Defendants Pharmacists # 1–100 for actions that are negligence per se because Defendants Pharmacies # 1–100 and Defendants Pharmacists # 1–100 have and will violate different provisions of the Ohio Pure Food and Drug Act, § 3715.01 *et seq.*, in the course of compounding and otherwise providing drugs to be administered to Plaintiff and that will kill him.
1770. Plaintiff does not bring either a civil cause of action under § 2307.60 or a civil tort claim in the above-captioned case against any of the Defendants. Rather, he seeks a declaratory judgment under Ohio Revised Code § 2721.02 to declare his and Defendants' rights, status and other legal relations—specifically a declaratory judgment that Defendants' actions violate the provisions of Ohio law as alleged herein, thus giving rise to Plaintiff's right to a civil cause of action under § 2307.60 and to a right to tort claims under Ohio law.
1771. Plaintiff also seeks injunctive relief as against the Drug Source Defendants. Plaintiff is not, however, seeking in this suit injunctive relief against DRC Defendants under Ohio law for violations of Ohio law.
1772. Defendants' actions in respect to Plaintiff's execution by lethal injection, identified in the preceding paragraphs, are offenses by

Defendants against Plaintiff under Ohio law that are of a criminal nature.

1773. Defendants' actions against Plaintiff include those that have been and are without privilege and are wanton and malicious, reckless, or negligent.
1774. Upon information and belief, the danger of Defendants' violations of Ohio state laws as against Plaintiff are present, actual and genuine; DRC Defendants intend to execute him using the Execution Protocol and, in the process, to violate Ohio state law as alleged herein.
1775. Pursuant to Ohio Revised Code § 2721.02(A), this Court has the authority to and should issue Declaratory Judgment for Plaintiff against Defendants, declaring that Defendants' actions and course of conduct to procure, manufacture, produce, process, export, import, compound, dispense, supply, use, administer, package, ship, store, sell, give away, offer for sale, or hold for sale lethal injection drugs, and Defendants' negligent, knowing, reckless, or wanton and malicious failures under the law associated with those efforts, constitutes one or more violations of Ohio law.
1776. Pursuant to Ohio Rev. Code § 2727.02, this Court has the authority to and should issue temporary, preliminary and permanent injunctive relief in Plaintiff's favor against Drug Source Defendants to restrain Drug Source Defendants' commission and continuance of violations of Ohio law against Plaintiff as alleged herein.

1777. Absent Plaintiff's receipt of such relief, Plaintiff would suffer great or irreparable harm as a result of Drug Source Defendants' many violations of Ohio state law, *see* Ohio Rev. Code § 2727.02, including violations of Plaintiff's rights as alleged in this Fourth Amended Omnibus Complaint, as well as death.

Eighteenth Cause of Action: Violation of Ohio Product Liability Act (Ohio Revised Code § 2307.71 et seq.)

1778. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Fourth Amended Omnibus Complaint as if fully rewritten here.
1779. Pursuant to Ohio Revised Code § 2307.71(A)(13), Ohio authorizes a "[p]roduct liability claim" to mean[] a claim or cause of action that is asserted in a civil action pursuant to sections 2307.71 to 2307.80 of the Revised Code and that seeks to recover compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question, that allegedly arose from any of the following: (a) The design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of that product."
1780. Ohio Revised Code § 2307.74 defines defective in manufacture as "[a] product is defective in manufacture or construction if, when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the

same design specifications, formula, or performance standards.” Ohio Revised Code § 2307.77 defines conformance to representation:

“[a]product is defective if it did not conform, when it left the control of its manufacturer, to a representation made by that manufacturer.”

1781. Ohio Revised Code § 2307.71(A)(9) defines manufacturer:

“‘Manufacturer’ means a person engaged in a business to design, formulate, produce, create, make, construct, assemble, or rebuild a product or a component of a product.”

1782. Ohio Revised Code § 2307.71(A)(15) defines supplier: “‘Supplier’ means, subject to division (A)(15)(b) of this section, either of the following: (i) A person that, in the course of a business conducted for the purpose, sells, distributes, leases, prepares, blends, packages, labels, or otherwise participates in the placing of a product in the stream of commerce.”

1783. Ohio Revised Code § 2307.77 provides: “A product is defective if it did not conform, when it left the control of its manufacturer, to a representation made by that manufacturer. A product may be defective because it did not conform to a representation even though its manufacturer did not act fraudulently, recklessly, or negligently in making the representation.”

1784. Ohio Revised Code § 2307.78(A)(2) provides: “The product in question did not conform, when it left the control of the supplier in question, to a representation made by that supplier, and that representation and

the failure to conform to it were a proximate cause of harm for which the claimant seeks to recover compensatory damages. A supplier is subject to liability for such a representation and the failure to conform to it even though the supplier did not act fraudulently, recklessly, or negligently in making the representation.”

1785. Upon information and belief, Drug Source Defendants manufactured drugs for sale to DRC Defendants for DRC Defendants’ use to attempt to execute Plaintiff.
1786. Upon information and belief, Drug Source Defendants sold or attempted to sell drugs to DRC Defendants for DRC Defendants’ use to attempt to execute Plaintiff.
1787. Upon information and belief, Drug Source Defendants are either manufacturers of lethal injection drugs or they are suppliers of lethal injection drugs as defined in Ohio Revised Code § 2307.71 or both.
1788. Upon information and belief, Drug Source Defendants misrepresented to DRC Defendants that the lethal injection drugs were manufactured to United States Pharmacopeia (USP) standards when indeed they were manufactured according to the lesser standards of the India Pharmacopeia (IP), the European Pharmacopeia (EUP, or the British Pharmacopeia (BP).
1789. Such deception as to the quality of the manufacturing process on the part of Drug Source Defendants as either manufacturers or suppliers constitutes a misrepresentation as to the products conforming to the

standard of manufacture which renders the lethal injection drugs defective products under Ohio Revised Code §§ 2307.77 and 2307.78(A)(2).

1790. As either manufacturers or suppliers or both, Drug Source Defendants are liable for compensatory damages arising from the use of this defective product. Plaintiff will be damaged by DRC Defendants' use of the defective products when DRC Defendants attempt to execute Plaintiff with a product that Drug Source Defendants misrepresented to be of a different manufacture and quality than that which was sold to DRC Defendants.
1791. Plaintiff will experience severe, unnecessary, lingering, and inhumane pain and suffering from the defective execution drugs manufactured or supplied by Drug Source Defendants.
1792. There is no practical method for Plaintiff to verify the quality, constitution, or uniformity of the execution drugs prior to being subjected to their lethal injection.
1793. There exists a substantial, objectively intolerable risk that these drugs are the wrong identity or pH level, ineffective, sub-potent, contaminated, unsterile, or otherwise adulterated.
1794. Accordingly, and for all the reasons discussed in this petition, use of execution drugs obtained from Drug Source Defendants for use under the Execution Protocol creates substantial, objectively intolerable risk of DRC Defendants inflicting unnecessary pain, suffering,

degradation, humiliation, and/or disgrace because on plaintiffs when DRC Defendants attempts to execute them with these drugs.

1795. Because there is no practical method to insure the purity of these defective drugs prior to their use, the use of any drugs manufactured or supplied by Drug Source Defendants must be permanently enjoined.

Nineteenth Cause of Action: Violation of Ohio Consumer Sales Practices Act (Ohio Revised Code § 1345.01 et seq.) Against Drug Source Defendants

1796. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Fourth Amended Omnibus Complaint as if fully rewritten here.
1797. The Ohio Consumer Sales Practices Act (OCSPA) states in pertinent part:

the act or practice of a supplier in representing any of the following is deceptive: [t]hat the subject of a consumer transaction has sponsorship, approval, performance characteristics, accessories, uses, or benefits that it does not have; [t]hat the subject of a consumer transaction is of a particular standard, quality, grade, style, prescription, or model, if it is not; and [t]hat the supplier has a sponsorship, approval, or affiliation that the supplier does not have.

Ohio Rev. Code §§ 1345.02(B)(1), (2), (9).

1798. A “consumer transaction” is defined as “a sale . . . or other transfer of an item or goods, a service, a franchise, or an intangible, to an individual for purposes that are primarily personal, family, or household, or solicitation to supply any of these things.” Ohio Rev.

- Code § 1345.01(A). A “supplier” is defined as “a seller, lessor, assignor, franchisor, or other person engaged in the business of effecting or soliciting consumer transactions, whether or not the person deals directly with the consumer.” Ohio Rev. Code § 1345.01(C).
1799. The goal of the OCSPA is to protect consumers. Therefore, it must be liberally construed in their favor. *Einhorn v. Ford Motor Co.*, 48 Ohio St. 3d 27, 29 (1990).
1800. “To establish a prima facie claim under the OCSPA, a plaintiff must ‘show a material misrepresentation, deceptive act or omission’ that impacted his decision to purchase the item at issue.” *Reeves v. PharmaJet, Inc.*, 846 F. Supp. 2d 791, 798 (N.D. Ohio 2012) (citing *Temple v. Fleetwood Enters., Inc.*, 133 Fed. Appx. 254, 265 (6th Cir. 2006) (citations omitted)).
1801. Under the OCSPA, deception is measured from the standpoint of the consumer asserting the claim. See *Ferron v. Echostar Satellite, LLC*, 727 F. Supp. 2d 647 (S.D. Ohio 2009), *aff’d*, 410 Fed. Appx. 903 (6th Cir. 2010).
1802. “In order to be deceptive, and therefore actionable, a seller’s act must not only be at variance with the truth but must also concern a matter that is or is likely to be material to a consumer’s decision to purchase the product or service involved.” *Richards v. Beechmont Volvo*, 127 Ohio App. 3d 188, 191 (1st Dist. 1998).

1803. A consumer does not, however, need to prove intent or scienter in order to prevail on a claim under the OCSPA. *Karst v. Goldberg*, 88 Ohio App. 3d 413, 417 (10th Dist. 1993).
1804. Upon information and belief, Drug Source Defendants have sold or attempted to sell to DRC Defendants execution drugs manufactured in a foreign country, including but not limited to India.
1805. Under Ohio Rev. Code § 1345.01 this is a consumer transaction. Under Ohio Rev. Code 1345.01(C), Drug Source Defendants who have engaged in this activity are “suppliers” as they have sold or attempted to sell a product—execution drugs—to a consumer—DRC.
1806. Upon information and belief, Drug Source Defendants have deceived DRC in selling or attempting to sell DRC execution drugs for use in Ohio executions.
1807. Upon information and belief Drug Source Defendants represented to DRC that execution drugs that Drug Source Defendants were to or did or will supply to DRC were manufactured according to USP standards.
1808. Upon information and belief, the execution drugs that Drug Source Defendants were selling or offering to sell to DRC were or will be actually manufactured to the lesser standards of Indian Pharmacopeia (IP) or European Pharmacopeia (EUP) or British Pharmacopeia (BP).

1809. Upon information and belief, DRC purchased or attempted to purchase the execution drugs based on the misrepresentations of Drug Source Defendants that the drugs were manufactured according to USP standards.
1810. Ohio Revised Code § 1345.01(B)(2) prohibits a supplier from misrepresenting “[t]hat the subject of a consumer transaction is of a particular standard, quality, grade, style, prescription, or model, if it is not.”
1811. Upon information and belief, Drug Source Defendants misrepresented the standard, quality, grade or prescription of the lethal injection drugs that they sold or attempted to sell to DRC in violation of Ohio Revised Code § 1345.01(B)(2).
1812. Plaintiff here is the ultimate consumer of the product sold by Drug Source Defendants to DRC and will be the ultimate party to suffer from the misrepresentations of Drug Source Defendants, as he will be the one who will physically suffer when DRC Defendants use these drugs to attempt to execute Plaintiff.
1813. Upon information and belief, Drug Source Defendants misrepresent or misrepresented the purity of the lethal injection drugs to DRC yet the ultimate consumer who will be harmed by the impure drugs is Plaintiff.

1814. The deceptive misrepresentations of Drug Source Defendants in misrepresenting that the lethal injection drugs that they claim to be manufactured to USP standards when in reality they are not must be enjoined to prevent ongoing harm to the ultimate consumers— Plaintiff, who will suffer when DRC Defendants attempt to execute him using impure execution drugs or drugs not manufactured to USP standards that were obtained from Drug Source Defendants.
1815. Ohio Revised Code § 1345.09(D) provides: “Any consumer may seek a declaratory judgment, an injunction, or other appropriate relief against an act or practice that violates this chapter.”
1816. Plaintiff therefore request that this Court enjoin Drug Source Defendants from misrepresenting the manufacturing standards for its drugs, and enjoin Drug Source Defendants from continuing to sell execution drugs to DRC that are not manufactured to USP standards.

ADDITIONAL CAUSES OF ACTION AGAINST ALL DEFENDANTS

Twentieth Cause of Action: Eighth Amendment Violation Based On Exposure To Sure Or Very Likely Serious Harm In The Form Of Severe, Needless Physical Pain And Suffering Due To The Identity Of The Drugs In The Execution Protocol.

1817. This claim alleging violations of the Eighth Amendment as incorporated against the states by the Fourteenth Amendment will be alleged in the Plaintiffs’ Amended Individual Supplemental Complaints to be filed in this case in accordance with the court’s scheduling order.

**Twenty-First Cause of Action: Eighth Amendment Violation
Based On Exposure To Sure Or Very Likely Serious Harm In The
Form Of Severe, Needless Physical Pain And Suffering Due To The
Source Of The Drugs In The Execution Protocol.**

1818. This claim alleging violations of the Eighth Amendment as incorporated against the states by the Fourteenth Amendment will be alleged in the Plaintiffs' Amended Individual Supplemental Complaints to be filed in this case in accordance with the court's scheduling order.

**Twenty-Second Cause of Action: Eighth Amendment Violation
Based On Sure Or Very Likely Exposure To Serious Harm In The
Form Of Severe Mental Or Psychological Pain, Suffering And
Torturous Agony Due To The Identity Of The Drugs In The
Execution Protocol.**

1819. This claim alleging violations of the Eighth Amendment as incorporated against the states by the Fourteenth Amendment will be alleged in the Plaintiffs' Amended Individual Supplemental Complaints to be filed in this case in accordance with the court's scheduling order.

**Twenty-Third Cause of Action: Eighth Amendment Violation
Based On Sure Or Very Likely Exposure To Serious Harm In The
Form Of Severe Mental Or Psychological Pain, Suffering And
Torturous Agony Due To The Source Of The Drugs In The
Execution Protocol.**

1820. This claim alleging violations of the Eighth Amendment as incorporated against the states by the Fourteenth Amendment will be alleged in the Plaintiffs' Amended Individual Supplemental Complaints to be filed in this case in accordance with the court's scheduling order.

**Twenty-Fourth Cause of Action: Eighth Amendment Violation
Based On Sure Or Very Likely Exposure To Serious Harm In The
Form Of A Lingering Death.**

1821. This claim alleging violations of the Eighth Amendment as incorporated against the states by the Fourteenth Amendment will be alleged in the Plaintiffs' Amended Individual Supplemental Complaints to be filed in this case in accordance with the court's scheduling order.

**Twenty-Fifth Cause of Action: Eighth Amendment Violation
Based On Sure Or Very Likely Exposure To Serious Harm In The
Form Of Being The Subject Of An Undignified, Spectacle
Execution Or Attempted Execution.**

1822. This claim alleging violations of the Eighth Amendment as incorporated against the states by the Fourteenth Amendment will be alleged in the Plaintiffs' Amended Individual Supplemental Complaints to be filed in this case in accordance with the court's scheduling order.

**Twenty-Sixth Cause of Action: Eighth Amendment Violation
Based On Sure Or Very Likely Exposure To Serious Harm in the
Form of Being Subjected to an Unwanted, Non-Consensual Human
Experimentation of an Execution.**

1823. This claim alleging violations of the Eighth Amendment as incorporated against the states by the Fourteenth Amendment will be alleged in the Plaintiffs' Amended Individual Supplemental Complaints to be filed in this case in accordance with the court's scheduling order.

Twenty-Seventh Cause of Action: Eighth Amendment Violation Based On Sure Or Very Likely Exposure To Serious Harm in the Form of Maladministration or Arbitrary Administration of the Execution Protocol.

1824. This claim alleging violations of the Eighth Amendment as incorporated against the states by the Fourteenth Amendment will be alleged in the Plaintiffs' Amended Individual Supplemental Complaints to be filed in this case in accordance with the court's scheduling order.

Twenty-Eighth Cause of Action: Eighth Amendment Violation Based On Sure Or Very Likely Exposure To Serious Harm In The Form Of Being Subjected To An Execution Protocol That Is Facially Unconstitutional Because It Does Not Preclude The Execution Of An Inmate That Is Categorically Exempt From Execution.

1825. This claim alleging violations of the Eighth Amendment as incorporated against the states by the Fourteenth Amendment will be alleged in the Plaintiffs' Amended Individual Supplemental Complaints to be filed in this case in accordance with the court's scheduling order.

Twenty-Ninth Cause of Action: Eighth Amendment Violation Based on Deliberate Indifference or Reckless Disregard of Substantial Risk of Harm to Plaintiff.

1826. This claim alleging violations of the Eighth Amendment as incorporated against the states by the Fourteenth Amendment will be alleged in the Plaintiffs' Amended Individual Supplemental Complaints to be filed in this case in accordance with the court's scheduling order.

Thirtieth Cause of Action: Fourteenth Amendment Due Process Violation For Failure To Comply With Federal Investigational New Drug Application Regulations With Respect To The Method And Choice Of Drug To Be Used In Plaintiff's Execution.

1827. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Fourth Amended Omnibus Complaint as if fully rewritten here.
1828. Federal and Ohio state law prohibit marketing and distributing any “new drug” in interstate commerce unless FDA has received and approved a “new drug application” (“NDA”) that demonstrates the drug is safe and effective for a specific use or uses. 21 U.S.C. § 355(a), Ohio Rev. Code § 3715.65.
1829. If the sponsor of a new drug wishes to market the drug for additional uses not previously approved by FDA—including for example different combinations or doses—the sponsor is required to submit a separate NDA to FDA.
1830. There is no approved NDA for thiopental sodium.
1831. The approved NDA for pentobarbital does not include its use for lethal-injection human executions, and does not include its use at the doses required by the Execution Protocol.
1832. The approved NDA for midazolam does not include its use for lethal-injection human executions, and does not include its use at the doses required by the Execution Protocol.

1833. The approved NDA for pancuronium bromide does not include its use for lethal-injection human executions, and does not include its use at the doses required by the Execution Protocol.
1834. The approved NDA for vecuronium bromide does not include its use for lethal-injection human executions, and does not include its use at the doses required by the Execution Protocol.
1835. The approved NDA for rocuronium bromide does not include its use for lethal-injection human executions, and does not include its use at the doses required by the Execution Protocol.
1836. The approved NDA for potassium chloride does not include its use for lethal-injection human executions, and does not include its use at the doses required by the Execution Protocol.
1837. Federal and Ohio state law provides an exception to the requirement of an approved NDA for clinical investigations of a new drug, including a new use of a previously approved drug. 21 U.S.C. § 355(i).
1838. Federal law provides FDA with explicit authority to promulgate regulations for the conditions and procedures for this investigational drug use, which are incorporated in 21 C.F.R. Part 312.
1839. Without such an exception, it would be illegal to move the drug in interstate commerce for purposes of a clinical investigation.
1840. FDA's regulations state that 21 C.F.R. Part 312 applies to all "clinical investigations" of new drugs. 21 C.F.R. § 312.1(a).
1841. Section 312.3(b) defines a "clinical investigation" as follows:

Clinical investigation means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.

21 C.F.R. § 312.3(b) (emphasis in original).

1842. This definition means that using a drug outside of medical practice constitutes a “clinical investigation,” and that even “medical practice” is limited to “marketed drugs.”
1843. Using a drug in the course of a lethal-injection execution is not “use of a marketed drug in the course of medical practice.”
1844. Under § 312.3(b), therefore, use of drugs under the Execution Protocol constitutes a clinical investigation under federal law, and requires the submission of an Investigational New Drug (“IND”) application.
1845. Part 312 requires that an IND application be submitted to FDA before a clinical investigation of a new drug is undertaken: “A sponsor *shall* submit an IND to FDA if the sponsor intends to conduct a clinical investigation with an investigational new drug that is subject to 312.2(a).” 21 C.F.R. § 312.20(a) (emphasis added).
1846. An “investigational new drug” is defined under the law as a “new drug” used in a “clinical investigation.” 21 C.F.R. § 312.2(a).
1847. The “sponsor” is “a person who takes responsibility for and initiates a clinical investigation.” 21 C.F.R. § 312.3(b).
1848. Under this definition, DRC Defendants and/or Drug Source Defendants are a “sponsor” of a “clinical investigation” for the drugs’

use in a lethal-injection execution, and are thus required by law to submit an IND to FDA for this investigational use.

1849. Subpart B of Part 312 specifies the IND requirements, including the requirement that a protocol be submitted to FDA as part of the IND application. 21 C.F.R. § 312.23(a)(6).
1850. DRC Defendants must include their Execution Protocol in the IND submission to FDA and ensure that the Execution Protocol complies with the applicable, detailed regulatory requirements.
1851. Drug Source Defendants must include their relevant protocols in the IND submission to FDA and ensure that their protocols comply with the applicable, detailed regulatory requirements.
1852. Defendants are not entitled to the statutory exception to the requirement of an IND application for clinical investigations of drugs that are “lawfully marketed” in the United States. *See* 21 C.F.R. § 312.2(b)(iii)–(iv).
1853. Drugs that are compounded are not considered “lawfully marketed” for purposes of the regulations related to the IND requirements:

Studies that use a drug product that is prepared from *raw materials in place of the approved, finished product marketed by the manufacturer must be conducted under an IND* (21 C.F.R. part 312). These studies cannot meet the criteria for an exemption from the IND requirements for marketed drugs (§312.2(b)) because the drug product manufactured by the investigator or research pharmacy *is not considered to be the lawfully marketed drug.*

FDA, Guidance for Clinical Investigators, Sponsors, IRBs: Investigational New Drug Applications (INDs)—Determining Whether Human Research Studies Can Be Conducted Without an IND (Sept. 2013) at 17 (emphasis added), available at

<http://www.fda.gov/downloads/Drugs/Guidances/UCM229175.pdf>.

1854. In accordance with the law, Defendants must submit an IND application and comply with the other IND requirements 30 days before putting the Execution Protocol into effect for a lethal-injection execution.
1855. The federal IND regulations preempt any Ohio state laws, including the Execution Protocol and § 2949.22(a), that are read to authorize Defendants to conduct lethal injections pursuant to protocols that have not first been submitted to FDA for review as part of an IND, because such Ohio state laws would be in direct and positive conflict with federal law. 1962 Drug Amendments, Pub. L. 87-781, 76 Stat. 780, 793, § 202.
1856. The federal regulatory safeguards employed in the IND requirements were designed to ensure the rights and welfare of persons in this

- country to whom medications or drugs may be administered, including but not limited to human subjects of experimentation and clinical investigation.
1857. Plaintiff is a person in the United States to whom any of the drugs in 01-COM-11 will be administered.
1858. Plaintiff is also the involuntary and coerced participant in Defendants' experimentation and clinical investigations, but he is, nevertheless, still the human subject of the clinical investigation and experimentation.
1859. The IND regulations contain no exception to the mandatory IND application process for any drug on the basis that it is used in a human execution.
1860. DRC Defendants are not exempt from the IND application regulations as it relates to execution drugs.
1861. Drug Source Defendants that are acting as 503A compounders are not exempt from the IND application framework as it relates to execution drugs due to their failure to comply with all relevant and applicable statutes and regulations, including but not limited to the requirements of USP 797 and the requirements that compounded drug products produced by a 503A compounding may only be compounded pursuant to a legally valid prescription.
1862. Drug Source Defendants that are acting as 503B outsourcing facilities are not exempt from the IND application framework as it relates to

compounded pentobarbital due to their failure to comply with all relevant and applicable statutes and regulations, including but not limited to the requirements of cGMPs and the prohibition on compounding any product that is a copy or essentially a copy of an approved drug.

1863. Until the moment of death, Plaintiff maintains a constitutionally protected residual life interest; all facets of the process by which Defendants seek to deprive him of that interest, therefore, must comply with the requirements of due process.
1864. Plaintiff has a due process right to be assured that Defendants have complied with the federal IND regulations with respect to the method and choice of drug to be used in his execution.
1865. Defendants know or should know that they are subject to the mandatory IND application regulations.
1866. Defendants intentionally, with deliberate indifference, and/or recklessly disregard the mandatory IND application regulations and have not submitted a satisfactory IND to the federal FDA regarding their experimental use of any of the execution drugs in their Execution Protocol, whether manufactured or compounded.
1867. Defendants intentionally, with deliberate indifference, and/or recklessly disregard the mandatory IND application regulations and, upon information and belief, will not submit a satisfactory IND to the federal FDA regarding their experimental use of any of the execution

drugs in their Execution Protocol, whether manufactured or compounded.

1868. Defendants' failure to comply with FDA's IND regulations related to the Execution Protocol deprive Plaintiff of a life interest without due process of law in violation of the Fourteenth Amendment.

Thirty-First Cause of Action: Equal Protection Violations Related To Defendants' Failures To Comply With The IND Application Laws.

1869. Plaintiff incorporates by reference each and every statement and allegation set forth throughout this Fourth Amended Omnibus Complaint as if fully rewritten here.
1870. Plaintiff, individually and as a member of a class of persons subject to a death sentence under Ohio law, has fundamental rights, such as those identified herein, and the fundamental due process rights identified herein.
1871. Plaintiff is similarly situated to others that will be human subjects of experimental and clinical investigations of Investigational New Drugs.
1872. Defendants' failures to comply with mandatory federal and Ohio state laws related to the IND application requirements are deviations from Core Elements of the Execution Protocol for the same reasons articulated herein.
1873. Defendants' intentional, deliberately indifferent, and/or reckless failure to follow the mandatory federal and Ohio state law IND application requirements treats Plaintiff disparately from others

similarly situated, thereby substantially burdening Plaintiff's fundamental rights in the ways identified herein and by burdening his fundamental right to a life interest in being assured that Defendants have complied with the federal IND regulations with respect to the method and choice of drug to be used in his execution before they attempt to execute him.

1874. Plaintiff is also a class of one, similarly situated with those protected from harm as subjects of human experimentation and clinical investigations by the federal IND application regulations.
1875. Defendants intentionally treat Plaintiff differently than similarly situated individuals by their arbitrary and irrational failure to follow the mandatory IND application regulations, thus irrationally subjecting Plaintiff to a heightened risk that he will suffer deprivations of his fundamental rights identified above without legitimate or rational reason.

Thirty-Second Cause of Action: First Amendment Free Exercise Clause and RLUIPA Violation.

1876. This claim alleging violations of the First Amendment as incorporated against the states by the Fourteenth Amendment and violations of the federal religious-freedom statutes will be alleged in the Plaintiffs' Amended Individual Supplemental Complaints to be filed in this case in accordance with the court's scheduling order.

Thirty-Third Cause of Action: Eighth Amendment Violations Based On Sure Or Very Likely Exposure To Severe Needless Physical Or Mental/Psychological Pain And Suffering Due To Plaintiff's Unique, Individual Characteristics And Application Of The Execution Protocol.

1877. This claim alleging violations of the Eighth Amendment as incorporated against the states by the Fourteenth Amendment will be alleged in the Plaintiffs' Amended Individual Supplemental Complaints to be filed in this case in accordance with the court's scheduling order.

Thirty-Fourth Cause of Action: Equal Protection Violations Related To Plaintiff's Unique, Individual Characteristics And Application Of The Law, Including DRC Defendants' Execution Protocol and Ohio's Execution Statute.

1878. This claim alleging violations of the Fourteenth Amendment's Equal Protection Clause will be alleged in the Plaintiffs' Amended Individual Supplemental Complaints to be filed in this case in accordance with the court's scheduling order.

Thirty-Fifth Cause of Action: Eighth Amendment Violation Based On Purposeful or Knowing Adoption of a Lethal Injection Protocol Using A Three-Drug Method With Midazolam As The First Drug That Will Cause Severe Physical Pain and Torturous Mental Anguish and Suffering.

1879. This claim alleging violations of the Eighth Amendment as incorporated against the states by the Fourteenth Amendment will be alleged in the Plaintiffs' Amended Individual Supplemental Complaints to be filed in this case in accordance with the court's scheduling order.

Thirty-Sixth Cause of Action: Eighth Amendment Violation Based On Purposeful or Knowing Adoption of a Lethal Injection Protocol Using Midazolam That Will Cause Severe Physical Pain and Torturous Mental Anguish and Suffering.

1880. This claim alleging violations of the Eighth Amendment as incorporated against the states by the Fourteenth Amendment will be alleged in the Plaintiffs' Amended Individual Supplemental Complaints to be filed in this case in accordance with the court's scheduling order.

Thirty-Seventh Cause of Action: Eighth Amendment Violations Based on DRC Defendants Resurrecting Their Abandoned Three-Drug Method Even Though They Know It Causes Needless Pain And Suffering, And Had Abandoned It, At Least In Part, For That Reason.

1881. This claim alleging violations of the Eighth Amendment as incorporated against the states by the Fourteenth Amendment will be alleged in the Plaintiffs' Amended Individual Supplemental Complaints to be filed in this case in accordance with the court's scheduling order.

Thirty-Eighth Cause of Action: Eighth Amendment Violation Based On Devolving Standards of Decency

1882. This claim alleging violations of the Eighth Amendment as incorporated against the states by the Fourteenth Amendment will be alleged in the Plaintiffs' Amended Individual Supplemental Complaints to be filed in this case in accordance with the court's scheduling order.

Thirty-Ninth Cause of Action: Eighth Amendment Violation Based On DRC Defendants' Use Of A Three-Drug Execution Method, Regardless Of The Identity Of The First Drug.

1883. This claim alleging violations of the Eighth Amendment as incorporated against the states by the Fourteenth Amendment will be alleged in the Plaintiffs' Amended Individual Supplemental Complaints to be filed in this case in accordance with the court's scheduling order.

Fortieth Cause of Action: Eighth Amendment Violation Based On DRC Defendants' Use Of A Three-Drug Execution Method With Midazolam As The First Of The Three Drugs.

1884. This claim alleging violations of the Eighth Amendment as incorporated against the states by the Fourteenth Amendment will be alleged in the Plaintiffs' Amended Individual Supplemental Complaints to be filed in this case in accordance with the court's scheduling order.

Forty-First Cause of Action: Eighth Amendment Violation Based On DRC Defendants' Use Of Midazolam In The Execution Protocol.

1885. This claim alleging violations of the Eighth Amendment as incorporated against the states by the Fourteenth Amendment will be alleged in the Plaintiffs' Amended Individual Supplemental Complaints to be filed in this case in accordance with the court's scheduling order.

Forty-Second Cause of Action: Eighth Amendment Violation Based On DRC Defendants Removal Of Any Required Concentration Of The Execution Drugs Which Is Removal Of A Safeguard That Makes It Sure Or Very Likely That Plaintiff Will Experience Severe Pain And Suffering.

1886. This claim alleging violations of the Eighth Amendment as incorporated against the states by the Fourteenth Amendment will be alleged in the Plaintiffs' Amended Individual Supplemental Complaints to be filed in this case in accordance with the court's scheduling order.

Forty-Third Cause of Action: The Doctrines Of Judicial Estoppel And/Or Judicial Admission Bar DRC Defendants From Using The Three-Drug Method Against Plaintiff.

1887. Plaintiff does not allege a Forty-Third Cause of Action.

Forty-Fourth Cause of Action: Administrative Procedures Act Claims

1888. Plaintiff does not allege a Forty-Fourth Cause of Action.

Forty-Fifth Cause of Action: Eighth and Fourteenth Amendment Violations—A three-drug midazolam method of execution violates the Eighth Amendment's prohibition against cruel and unusual punishment because it no longer comports with prevailing standards of decency, and thus its use as a method of execution must be categorically barred.

1889. This claim alleging violations of the Eighth Amendment as incorporated against the states by the Fourteenth Amendment will be alleged in the Plaintiffs' Amended Individual Supplemental Complaints to be filed in this case in accordance with the court's scheduling order.

**Forty-Sixth Cause of Action: Ohio Corrupt Practices Act Claims
Against Individual Defendants in Their Individual Capacity**

1890. Plaintiff does not allege a Forty-Sixth Cause of Action.

**Forty-Seventh Cause of Action: Equal Protection Clause Violation
based on violations of Administrative Procedures Act**

1891. Plaintiff does not allege a Forty-Seventh Cause of Action.

PRAYER FOR RELIEF

- A. Plaintiff requests that this Court grant him injunctive relief under federal law in the form of the following:
- a. preliminary and permanent prohibitive injunctions preventing Defendants from executing him by means of any part of their execution policy, including the 2016 Execution Protocol or any other execution policy, new or old, formal or informal which, as written or as administered, violates his federal constitutional rights;
 - b. preliminary and permanent mandatory injunctions requiring Defendants to adopt, and adhere in their administration to, a facially constitutional written execution protocol in efforts to execute him, and that such written execution protocol must formally adopt the Incident Command Systems principles and application in the execution context as a formal element of Defendants' written execution protocol;
 - c. preliminary and permanent prohibitive injunctions preventing Defendants from executing him by means of their execution policy, including the 2016 Execution Protocol or any other execution policy, new or old, formal and/or informal that is facially unconstitutional, including facial unconstitutionality for failure to ensure that an unconstitutional execution is not carried out;

- d. preliminary and permanent prohibitive injunctions preventing Defendants from executing him by means of an execution policy, including the 2016 Execution Protocol or any other execution policy, new or old, formal and/or informal, that is unconstitutional as applied to him, including as-applied unconstitutionality for failure to ensure that an unconstitutional execution is not carried out;
- e. preliminary and permanent prohibitive injunctions preventing Defendants from executing him by means of an execution policy, including the 2016 Execution Protocol or any other execution policy, new or old, formal or informal, that involves or allows any use of execution drugs manufactured by compounding or using compounding methods, or that involves or allows any use of pharmacists or pharmacies to manufacture the execution drug(s) via compounding, or that involves or allows any use of execution drugs manufactured by any pharmacist or pharmacy;
- f. preliminary and permanent prohibitive injunctions preventing Defendants from executing him by means of an execution policy, including the 2016 Execution Protocol or any other execution policy, new or old, formal and/or informal, that involves or allows any use of execution drugs manufactured by compounding or using compounding methods, or that involves or allows any use of pharmacists or pharmacies to manufacture the execution drug(s)

via compounding, or that involves or allows any use of execution drugs manufactured by any pharmacist or pharmacy when such pharmacist and the relevant drug-making facility have not been before use in any execution, inspected, investigated, tested and analyzed in ways detailed in this Fourth Amended Omnibus Complaint;

- g. preliminary and permanent prohibitive injunctions preventing Defendants from executing him by means of an execution policy, including the 2016 Execution Protocol or any other execution policy, new or old, formal and/or informal, that involves or allows any use of execution drugs manufactured by compounding or using compounding methods, or that involves or allows any use of pharmacists or pharmacies to manufacture the execution drug(s) via compounding, or that involves or allows any use of execution drugs manufactured by any pharmacist or pharmacy, when such drugs and Defendants' related actions have not been, before use in any execution, inspected, tested and analyzed by an independent entity approved by Plaintiff, to ensure that the drugs are pure, unadulterated, uncontaminated, not expired or beyond-use-date, of the exact type, potency, and concentration, not imported (including not manufactured using imported raw API), and not manufactured, prepared, mixed, assembled, labeled, packaged,

- stored, transferred, distributed, acquired, or any other such matter, in a way that violates any federal or State of Ohio laws;
- h. preliminary and permanent prohibitive injunctions preventing Defendants from executing him by means of their execution policy and written Execution Protocol to which they have failed to strictly adhere;
- i. preliminary and permanent prohibitory injunctions barring Defendants from executing him by a means that will deny his liberty, life, and property interests in the expectation and receipt of a quick, painless, humane and dignified death, which interests are guaranteed by Ohio Rev. Code § 2949.22(A) and DRC Policy 01-COM-11 and protected by the substantive and procedural elements of the Due Process Clause of the federal constitution's Fourteenth Amendment;
- j. preliminary and permanent prohibitory injunctions barring Defendants from executing him by a means that will deny any other fundamental rights as alleged herein;
- k. preliminary and permanent mandatory injunctions requiring Defendants to comply with all training and Execution Team personnel requirements set forth in the written Execution Protocol, and prohibiting supervisory personnel from allowing Execution Team member participation in any execution without full compliance with all of the written protocol's substantive training

requirements, execution rehearsal training requirements, and other mandatory provisions;

1. preliminary and permanent prohibitory injunctions as necessary to effectuate Campbell's entitlement to relief under the doctrines of judicial estoppel, judicial admission and/or promissory estoppel, and barring Defendants from executing Campbell using the three-drug method;
- m. preliminary and permanent prohibitive injunctions preventing Defendants from enforcing those provisions of their execution policy and written Execution Protocol that violate Plaintiff's First Amendment rights to free speech;
- n. preliminary and permanent prohibitive injunctions preventing Defendants from executing him by means of an execution policy, including the 2016 Execution Protocol or any other execution policy, new or old, formal and/or informal, that fails to ensure and protect his Due Process right to know, well in advance, the method of execution by which Defendants will attempt to execute him; the source of the drug(s) with which Defendants will attempt to execute him; all relevant information regarding the involvement of any Drug Source Defendants; whether the drug(s) to be used to execute him are pure, unadulterated, uncontaminated, not expired/beyond their labeled use date, of the exact type, potency, and concentration, not imported (including not manufactured

using imported raw API), and not manufactured, prepared, mixed, assembled, labeled, packaged, stored, transferred, distributed, acquired, or any other such matter, in a way that violates any federal or State of Ohio laws;

- o. preliminary and permanent prohibitive injunctions preventing Defendants from attempting to conduct any further executions until such time as the Court orders otherwise;
- p. preliminary and permanent injunctions prohibiting Drug Source Defendants from supplying DRC Defendants with drugs that do not comply with all federal and state law
- q. Preliminary and permanent injunctions prohibiting Drug Source Defendants from engaging in actions that violate federal and Ohio state law.

B. Plaintiff requests that this Court grant him declaratory relief under federal law in the form of the following:

- a. an Order declaring that Defendants' execution policy and written execution protocol will subject him to a substantial risk of harm, including severe physical and/or psychological pain, needless suffering, and a torturous, lingering, undignified, and/or spectacle execution or attempted execution, and/or an objectively intolerable risk of such harm that Defendants unjustifiably ignore, resulting in cruel and unusual punishment, whether that method is through the policy's Plan 1, Plan 2 or Plan 3, and that Defendants'

execution policy and written Execution Protocol fails to ensure against an execution that would constitute cruel and unusual punishment, and will thus violate Plaintiff's rights under the Eighth and Fourteenth Amendments to the United States Constitution;

- b. an Order declaring that Defendants' substantial, documented and admitted deviations and/or pattern of deviations and/or variations from their written Execution Protocol and the safeguards contained therein, as applied in Defendants' execution policy before, during and after administration of the execution policy, creates a substantial risk of harm, including severe physical and/or psychological pain, needless suffering, and a torturous, lingering, undignified, and/or spectacle execution or attempted execution, and/or an objectively intolerable risk of such harm that Defendants unjustifiably ignore, in violation of Plaintiff's rights under the Eighth and Fourteenth Amendments;
- c. an Order declaring that Defendants' execution policy and written Execution Protocol denies his life, liberty and property interests in expecting and receiving a quick, painless, humane and dignified death, which interests are created under binding state law in the form of Ohio Revised Code § 2949.22 and/or DRC Policy 01-COM-11, and protected as rights by the substantive and procedural elements of the Fourteenth Amendment's Due Process Clause,

resulting in denial of his substantive and procedural due process rights;

- d. an Order declaring that Defendants' substantial and demonstrated deviations and/or pattern of deviations and/or variations from their execution policy and written Execution Protocol before, during and after administration of the policy and protocol are not necessary to achieve any compelling state interest, and that such deviations and/or variations substantially burden the fundamental rights of the class of persons of condemned inmates subject to a death sentence imposed in Ohio state courts—which includes Plaintiff—under the First, Sixth, Eighth, Ninth and Fourteenth Amendments, in violation of his rights to equal protection under the Fourteenth Amendment to the United States Constitution;
- e. an Order declaring that Defendants' substantial and demonstrated deviations and/or pattern of deviations and/or variations from their execution policy and written execution protocol before, during and after administration of the policy and protocol, are unrelated to any legitimate governmental interest, and arbitrarily and irrationally treat or will treat Plaintiff as a class of one differently than others similarly situated, in violation of his rights to equal protection under the Fourteenth Amendment to the United States Constitution;

- f. an Order declaring that Defendants' execution policy and written Execution Protocol facially violate Plaintiff's rights protected by the Fourteenth Amendment's Equal Protection Clause because they allow Defendants to treat similarly situated individuals differently, such disparate treatment burdens the fundamental rights of the class of persons of condemned inmates subject to a death sentence imposed in Ohio state courts—which includes Plaintiff—under the First, Sixth, Eighth, Ninth and Fourteenth Amendments, and it is not necessary to achieve a compelling state interest;
- g. an Order declaring that Defendants' execution policy and written Execution Protocol facially violate Plaintiff's rights as a class of one protected by the Fourteenth Amendment's Equal Protection Clause because they allows Defendants to treat Plaintiff differently than similarly situated individuals, without any legitimate governmental interest, irrationally and arbitrarily;
- h. an Order declaring that Plaintiff and other condemned inmates have fundamental, unenumerated rights that arise under the principles of liberty and natural law, and these rights are protected by the Ninth Amendment to the United States Constitution, and that Defendants' execution policy and written Execution Protocol, as written and as applied, violate those fundamental rights in violation of the Ninth Amendment;

- i. an Order declaring that Plaintiff and other condemned inmates have a fundamental right against being forced to be unwilling, non-consenting subjects of human experimentation that is guaranteed by the fact of their status as United States citizens and protected by the Privileges or Immunities Clause of the Fourteenth Amendment, and that Defendants' Execution Protocol, as written and as applied, violates that fundamental right;
- j. an Order declaring that those portions of Defendants' execution policy and written Execution Protocol that provide discretion to governmental actors to impose restrictions on the content and length of any last statement given before an execution attempt are, facially and as applied, impermissible content-based restrictions, and/or violations of the public forum and/or limited public forum doctrines, and therefore in violation of Plaintiff's rights to free speech under the First Amendment;
- k. an Order declaring that Plaintiff's right to due process requires that Defendants notify him no less than 30 days before his scheduled execution of: which method of execution Defendants will use; whether Defendants will use execution drugs manufactured by compounding methods and/or manufactured by a pharmacist or pharmacy; which pharmacist will make the execution drug(s) to be used for his execution; and all other relevant information;

1. an Order requiring full testing, investigation, analysis, and inspection related to any compounded execution drug(s) and any Drug Source Defendants and their manufacturing facility to be involved in any way related to an execution in Ohio, to be done by an independent party not affiliated or connected or related in any way to the government of the State of Ohio or any Defendants or their agents under 01-COM-11;
 - m. an Order declaring that the reasoning and analysis in any prospective opinion issued by this Court temporarily and preliminarily enjoining Defendants from executing him applies to preclude Defendants from attempting any further executions until such time as the Court orders otherwise;
 - n. an Order declaring that Defendants are barred under the doctrines of judicial estoppel, judicial admission and/or promissory estoppel from executing Campbell using the three-drug method; and
 - o. Such other declaratory relief as Plaintiff may subsequently request.
- C. Plaintiff requests that this Court grant him declaratory relief under Ohio state law in the form of a declaration that Defendants' actions related to execution drugs are violating or will violate federal and state statutes and administrative regulations.
- D. Plaintiff requests that this Court grant such further relief as otherwise requested herein.

- E. Plaintiff requests that this Court grant such further relief as it deems just and proper.
- F. Plaintiff requests that this Court grant him reasonable attorney fees under 42 U.S.C. § 1988 and the laws of the United States, as applicable.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, Plaintiff demands a trial by jury of all issues so triable.

Respectfully submitted,

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by

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I hereby certify that on September 22, 2017, I filed the foregoing
**FOURTH AMENDED OMNIBUS COMPLAINT FOR INJUNCTIVE AND
DECLARATORY RELIEF, ATTORNEY FEES AND COSTS OF SUIT
PURSUANT TO 42 U.S.C. § 1983 AND OTHER RELATED CAUSES OF
ACTION** electronically with the Clerk of the United States District Court for the Southern District of Ohio using the CM/ECF system, which will send notification of such filing to the following opposing counsel at the e-mail address on file with the Court:

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